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IN THE

Supreme Court of the United States

ELIZABETH KEMP AND CLIFFORD KEMP,
Petitioners,

v.

MEDTRONIC, INC.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

In *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the Court held that the state-law damages claims at issue there were not preempted by the Medical Device Amendments ("MDA") to the Food Drug and Cosmetic Act, 21 U.S.C. 360k(a). The Court did not, however, explicitly decide whether its no-preemption ruling applies where the medical device alleged to have caused the plaintiff's injury has been granted pre-market approval by the Food and Drug Administration ("FDA"). Since *Medtronic*, the lower federal courts and state courts of last resort are deeply divided over that question. *Compare, e.g., Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999) (no preemption); *Weiland v. Telectronics Pacing Sys., Inc.*, 721 N.E.2d 1149 (Ill. 1999) (same), *with, e.g., Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997) (preemption), *cert. denied*, 523 U.S. 1020 (1998); *Fry v. Allergan Medical Optics*, 695 A.2d 511 (R.I.) (same), *cert. denied*, 522 U.S. 952 (1997). In addition, the United States has taken the position that pre-market approval does not trigger preemption. *See infra* at 22.

The question presented is:

> Did the court below err in holding that petitioners' state-law damages claims are expressly preempted by the MDA solely on the ground that the FDA had granted pre-market approval for the medical device alleged to have caused petitioners' injuries?

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PETITION FOR A WRIT OF CERTIORARI

Petitioners Elizabeth Kemp and Clifford Kemp seek a writ of certiorari to challenge the Sixth Circuit's ruling that their state-law damages claims, alleging injuries caused by a medical device, are preempted by the Medical Device Amendments ("MDA") to the federal Food, Drug, and Cosmetic Act.

This Court should grant review for two related reasons. **First**, since the Court's decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the federal and state appellate courts are, in the Sixth Circuit's words (8a), "sharply divided" on the question presented here: whether state-law damages claims concerning medical devices that have been approved by the Food and Drug Administration ("FDA") under the MDA's pre-market approval ("PMA") process are preempted. In fact, two circuit courts have now reviewed the same FDA approval with respect to the same medical device, made by the same company, and reached exactly opposite results. *Compare Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999) (applying *Lohr* and finding no preemption of state-law damages claims), *with* 1a (Sixth Circuit decision below, applying *Lohr* and finding preemption of all state-law damages claims).

Second, the Court should grant review because a significant number of appellate courts have erroneously reaffirmed broad pre-*Lohr* interpretations of the MDA's preemption provision, 21 U.S.C. 360k(a). Like the Sixth Circuit below, these courts have mistakenly held that the FDA's approval of a PMA application constitutes a specific preemption-triggering federal "requirement" under section 360k(a) and have failed to follow *Lohr*'s holding that claims based on state-law duties of general applicability are not preempted. *See Lohr*, 470 U.S. at 501-02.

OPINIONS BELOW

The opinion of the Sixth Circuit is reported at 231 F.3d 216, and is reproduced in the appendix at 1a. The Sixth Circuit's unreported per curiam order denying petitioners' petition for rehearing and suggestion for rehearing en banc is reproduced in the appendix at 83a. The two relevant unreported decisions of the United States District Court for the Southern District of Ohio are reproduced at 43a and 70a.

JURISDICTION

The judgment of the Sixth Circuit affirming the grant of summary judgment in favor of respondent was entered on November 1, 2000 (1a). Petitioners filed a timely petition for rehearing with suggestion for rehearing en banc on November 14, 2000, which was denied on January 26, 2001 (83a). On April 18, 2001, Justice Stevens granted petitioners' application for an extension of time to file this petition for a writ of certiorari to and including May 26, 2001. This Court has jurisdiction under 28 U.S.C. 1254(1).

STATUTES AND REGULATIONS INVOLVED

21 U.S.C. 360k provides in part:

State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

> **(1)** which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> **(2)** which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 C.F.R. 808.1(d) provides in part:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act [21 U.S.C. 360k(a)] because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:
>
> (1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices....

STATEMENT OF THE CASE

In January 1992, petitioner Elizabeth Kemp was implanted with a pacemaker lead manufactured by respondent Medtronic, Inc. The lead is a wire that delivers an electrical impulse from a pacemaker's "pulse generator" to the patient's heart. Because of defects that ultimately led to withdrawal of the product from the market, Mrs. Kemp's lead failed, causing her to lose consciousness, collapse, and fall on the concrete floor of her garage. She sustained serious and permanent brain injuries from the fall that have required continuing medical care and rehabilitation. 2a-3a; Complaint, ¶¶ 8-14. In addition, Mrs. Kemp's husband, petitioner Clifford Kemp, suffered loss of consortium and other damages. 7a; Complaint, ¶ 62. This petition presents the question whether the Kemps may seek recovery for their injuries under Ohio law, or whether, as respondent maintains, the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act — enacted in 1976 to protect consumers from potentially dangerous medical devices — actually bar the Kemps from recovering their damages.

Part A below describes the structure of the MDA, and Part B explains the factual background and district court proceedings in this case. Part C discusses this Court's decision in *Medtronic v. Lohr, Inc.*, which interpreted the MDA's preemption provision and has spawned conflicting views in the state and federal appellate courts on the meaning of that provision. Finally, Part D describes the holding of the Sixth Circuit below.

A. The Medical Device Amendments.

The principal purpose of the MDA was to increase consumer protection by preventing the distribution of

dangerous medical devices and by providing a process by which devices could reach the market. H.R. Rep. 853, 94th Cong., 2d Sess. 1-12 (1976); *see* P.L. No. 94-295, 90 Stat. 539 (1976) (codified at 21 U.S.C. 360c *et seq.*). Every medical device falls into one of three classes. In general, as health risks from a device increase, so does regulatory scrutiny under the MDA. H.R. Rep. 853, *supra* at 34; 21 U.S.C. 360c(a). Class I devices, such as band aids, are the least risky and are subject only to "general controls" applicable to all devices, such as general labeling requirements and good manufacturing practices rules promulgated by the FDA, the agency charged by Congress with implementing the MDA. *See id.* § 360c(a)(1)(A).

Class II devices are more likely than class I devices to cause harm if they are defective or misused. *Id.* § 360c(a)(1)(B). Thus, the FDA may subject them to "special controls," such as the agency's specific warning labels for tampons. *See* 21 C.F.R. 801.430(c), (d) & (e).

Finally, class III devices — such as the pacemaker leads at issue here and in *Lohr* — are those that, in general, cannot be marketed until the FDA has found that the device presents a reasonable assurance of safety and effectiveness. 21 U.S.C. 360c(a)(1)(C). This process is known as pre-market approval, or PMA. *Id.* § 360e(b)(1)(A).[1]

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[1]Certain class III devices, such as the one at issue in *Lohr*, can be marketed without going through the full PMA process. If the FDA finds that a Class III device is "substantially equivalent" to a device marketed prior to the MDA's effective date, or to a device that itself was found to be "substantially equivalent" to a pre-MDA device, that device need not obtain PMA until the FDA issues a regulation

(continued...)

Three components of the regulatory structure are relevant to this petition. **First**, when it approves a manufacturer's PMA application, the FDA does not warrant that the device is free of defect in design, manufacture, or labeling. And, of critical importance here, the FDA does not, as part of the PMA process, require or specify the device's design, manufacturing process, or labeling, nor does it conduct testing or studies regarding the device. Rather, a device's design, manufacture, and labeling originate with the applicant (the device manufacturer), on whose data the FDA depends in acting on the PMA application. 21 C.F.R. 814.20, 814.44. As in this case, the FDA issues a form approval letter reminding the manufacturer of its obligations under federal regulations. There is nothing device-specific in the form approval letter.

Second, in a few instances, the FDA has issued device-specific requirements for particular types of devices. For instance, in addition to the tampon warning label mentioned above, the FDA has required that hearing aids bear certain labels and that tampon absorbency be tested in a specific manner. *See* 21 C.F.R. 801.420, 801.430(f). The FDA has never promulgated any such device-specific requirements for pacemakers or their component parts, such as the pacemaker lead that caused the Kemps' injuries.

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[1](...continued)
requiring PMA for that type of device. 21 U.S.C. 360e(b)(1)(B), 360c(f)(1)(A). The FDA's process for approving such devices is sometimes referred to as the "510(k)" process after the section of the Food, Drug, and Cosmetic Act under which the device application is submitted. *See Lohr*, 518 U.S. at 478.

Third, the MDA contains a preemption provision, 21 U.S.C. 360k(a), which preempts certain state-law "requirements" "with respect to a device" if they are "different from, or in addition to" MDA "requirements." Under 21 U.S.C. 360k(b), the FDA has the authority to exempt from preemption certain state requirements that would otherwise be preempted. Thus, the FDA has issued regulations concerning the scope of MDA preemption, *see generally* 21 C.F.R. Part 808, which reflect section 360k(a)'s narrow reach. *See Lohr*, 470 U.S. at 498 n.18 ("FDA's narrow understanding of the scope of § 360k(a) is obvious from the full text of the regulation"). For instance, the regulations require that for an FDA requirement to have preemptive effect, it must establish a device-specific "counterpart" to a "divergent" state-law requirement. 21 C.F.R. 808.1(d). Likewise, to be preempted, state-law requirements also must be "specific." Thus, preemption does not extend to state requirements of "general applicability where the purpose of the requirement relates ... to other products in addition to devices." *Id.* § 808.1(d)(1).

B. Background Facts and District Court Proceedings.

The product that caused Mrs. Kemp's injuries is Medtronic's 4004M pacemaker lead. 3a. The 4004M lead had its origins in an earlier model, the 4003, to which FDA granted pre-market approval in 1986. Later, respondent submitted to the FDA a "PMA supplement" for the 4004M lead, based in part on its 4003 application, but which contained new information, including that the metal coils in the lead would be coated with platinum designed to prevent degradation of the lead's polyurethane insulation. The FDA approved Medtronic's 4004M application in March 1990. 4a.

After the product's approval, it was discovered that the

4004M ran a significant risk of failure because the platinum coating failed to prevent degradation of its polyurethane insulation. As a result, in October 1993, respondent issued a "Health Safety Alert" to the medical community and withdrew the remaining 4004M leads from the market. 4a-5a. The Health Safety Alert did not direct doctors to remove the lead from patients in whom it had already been implanted. Mrs. Kemp's lead, therefore, was not explanted. In June 1995, Mrs. Kemp's lead suddenly failed, which, as noted above, caused her serious injuries.

In January 1997, the Kemps filed suit, based on diversity of citizenship under 28 U.S.C. 1332, in the United States District Court for the Southern District of Ohio. The complaint alleged that respondent was liable for the Kemps' damages, on strict liability and negligence grounds, for failing to properly manufacture, design, and test the 4004M lead. Complaint, ¶¶ 16-20 (Counts I and II). The Kemps also sought relief on the grounds that respondent made negligent misrepresentations regarding the lead to the Kemps and their doctors, *id.* ¶ 20, and that respondent failed to provide the Kemps with adequate warnings regarding the 4004M's insulation, the failures of that insulation, and the product's inadequate testing. *Id.* ¶ 27 (Count IV).[2]

In two separate opinions, the latter dealing solely with petitioners' claims of negligence per se (*see supra* note 2), the

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[2]The Kemps also made a claim of negligence per se under Ohio law, alleging that respondent violated certain federal regulations. *Id.* ¶ 23. The court of appeals ruled for respondent on the negligence per se claim on state-law grounds (84a), as well as on federal preemption grounds, and thus petitioners do not pursue that claim here.

district court held all of the Kemps' state-law claims preempted and granted summary judgment to respondent. 43a, 70a. The district court relied principally on the Sixth Circuit's earlier decision in *Martin v. Telectronics Pacing Sys., Inc.*, 105 F.3d 1090, 1095 (6th Cir. 1997), *cert. denied*, 522 U.S. 1075 (1998), which held that state-law damages claims regarding devices marketed under the MDA's investigational device approval process are expressly preempted by 21 U.S.C. 360k(a).

Petitioners appealed to the Sixth Circuit, arguing that their claims are not preempted under this Court's decision in *Lohr*. Because of the importance of *Lohr* to the issues presented in this petition, we now review that decision in detail, and then return to the Sixth Circuit's ruling.

C. The Decision in *Medtronic v. Lohr*

In *Lohr*, plaintiff Lora Lohr filed suit under Florida law for damages resulting from an allegedly defective class III pacemaker lead that the FDA had cleared for marketing under its "substantial equivalence" process. This Court held that none of Lohr's claims — based on defective design, defective manufacture, and failure to warn — was preempted by the MDA.

1. *The Majority Opinion.* Although there was a partial dissent in *Medtronic*, the majority opinion contains three holdings in which all members of the Court concurred: (1) The MDA does not broadly preempt all state-law damages claims against device manufacturers, *Lohr*, 470 U.S. at 480 (plurality); *id.* at 505 (Breyer, J., concurring in part and concurring in the judgment); *id.* at 513 (O'Connor, J., concurring in part and dissenting in part); (2) Lohr's design-defect claim was not preempted because the FDA had not issued any design specifications for the device in question, *id.* at 492-94

(majority); *id.* at 513 (O'Connor, J., concurring in part and dissenting in part); and (3) a tort claim premised on state-law duties "equal to, or substantially identical to, requirements" imposed under the MDA or FDA regulations are not preempted. *Id.* at 494-97 (majority); *id.* at 513 (O'Connor, J., concurring in part and dissenting in part).

By a 5-4 margin, the Court also held that Lohr's manufacturing-defect and failure-to-warn claims were not preempted, even if they did more than seek to enforce the federal requirements. The Court looked to the language of the MDA's preemption provision and the FDA's preemption regulations and noted the "overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest." *Id.* at 500. The generality of the FDA's manufacturing and labeling regulations applicable to the pacemaker lead, the Court held, precluded a finding of preemption. Those federal requirements, the Court said, reflect "important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect from potentially contradictory state requirements." *Id.* at 501.

The Court further noted that Lohr's damages claims were premised on general state-law duties that did not focus specifically on medical devices. Thus, the Court found, the general state-law duties to use due care in manufacturing and to warn users of potential risks are not the types of requirements that Congress or the FDA feared would impede the FDA's ability to enforce specific federal laws and regulations. Because they were based on general principles of state law, the majority held, the claims were outside of the prohibited category of state-law requirements "with respect to" specific

devices within the meaning of section 360k(a). *Id.* at 501-02.[3]

2. *The Concurrence.* Justice Breyer filed a concurring opinion stating that, in his view, section 360k(a)'s reference to state-law "requirements" encompasses state-law damages claims. He therefore did not join the plurality opinion (*see supra* note 3), because he was not convinced that MDA preemption of damages claims would be "rare." *Id.* at 508. He joined fully, however, in the analysis set forth above and in Part V of the majority opinion, which demanded specificity on both the state and federal sides of section 360k(a)'s preemption analysis. He stated that the applicable FDA requirements that were related to Lohr's claims were not "specific" in any relevant sense and deferred to the FDA's preemption regulation, 21 C.F.R. 808.1(d), which amplifies the meaning of section 360k(a)'s specificity requirement. 470 U.S. at 505-06 (citing, *e.g., Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-45 (1984)). He noted that the language of section 360k(a) reflected basic principles of conflict preemption, but found no conflict between any federal requirement and any of Lohr's claims. *Id.* at 506.

3. *The Partial Dissent.* Justice O'Connor dissented in part and concurred in part, joined by the Chief Justice and

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[3]Speaking for a four-Justice plurality, the lead opinion also relied on the MDA's language and history to conclude that section 360k(a) was not intended to preempt most, and perhaps any, damages claims. *Id.* at 488-91 (distinguishing *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992)). The plurality found it unnecessary to decide whether section 360k(a) reached any damages claims, however, because, under the majority's more focused analysis, none of Lohr's claims was preempted. *Id.* at 502-03.

Justices Scalia and Thomas. In her view, state-law damages claims can constitute "requirements" under section 360k(a). *Id.* at 509-11. Although concurring with the majority that Lohr's design-defect claim was not preempted, she would have held that the manufacturing-defect and failure-to-warn claims were preempted to the extent that they sought to impose requirements different from those imposed by the FDA's manufacturing and labeling rules. *Id.* at 513-14. She agreed with the majority that Lohr's manufacturing-defect and failure-to-warn claims were not preempted to the extent that they alleged violations of federal requirements. *Id.* at 513.

D. The Sixth Circuit's Decision.

In this case, the Sixth Circuit affirmed the grant of summary judgment to respondent on all of the Kemps' state-law damages claims. The court of appeals' decision reached two conclusions relevant to the question presented in this petition. **First**, the court held that the FDA's approval of respondent's PMA application for the 4004M lead, coupled with the FDA's form approval letter (17a), amounted to a specific preemption-triggering federal requirement within the meaning of 21 U.S.C. 360k(a) and this Court's decision in *Lohr*. In particular, it construed the FDA's approval of the 4004M PMA application as transforming the information regarding those topics contained in the application into a specific federal requirement. 20a-22a. The court thus held that a state-law damages claim based on a device's defective design or manufacture, or based on a claim that the device was accompanied by inadequate warnings, is preempted because of the perceived conflict between the purported federal requirement and the state-law damages claims. The court acknowledged that its holding was flatly at odds with the Eleventh Circuit's decision in *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999), which also involved the 4004M lead and which held that the FDA's pre-

market approval does not trigger preemption under section 360k(a). 15a (noting that *Goodlin* "addressed this exact issue on nearly indistinguishable facts"). *See also, e.g., Weiland v. Telectronics Pacing Sys., Inc.*, 721 N.E.2d 1149, 1153 (Ill. 1999) (also acknowledging direct conflict in appellate authority). In reaching its conclusion, the Sixth Circuit did not even mention the *Lohr* majority's holding that state-law duties of general applicability, such as those typically relied on in state-law damages claims, are not preempted by section 360k(a). *See Lohr*, 470 U.S. at 501-02.

Second, the court of appeals provided additional explanation for its holding that petitioners' failure to warn claim is preempted by the MDA. The court stated that, because petitioners alleged that respondent failed to warn of the malfunctions of the 4004M's insulation prior to Mrs. Kemp's injuries, "the claim was premised on the [in]adequacy of the warnings reviewed and approved by the FDA." 37a. Thus, in the Sixth Circuit's view, this claim is preempted because it would impose a requirement different from that imposed by the FDA. In this regard, the court did not cite, much less address, the FDA's regulation that permits a manufacturer to make label changes and provide additional warnings to enhance safety of PMA devices without prior FDA approval. 21 C.F.R. 814.39(d)(1) and (2) (cited as support for majority holding in *Lohr*, 470 U.S. at 497 n.16).[4]

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[4]The Sixth Circuit also held that petitioners' negligence per se claim is preempted (22a), but, as noted earlier (*see supra* note 2), that claim was also resolved on state-law grounds (84a) and is not presented here. The Sixth Circuit also held that petitioners' fraud-on-the-FDA claim is expressly preempted by 21 U.S.C. 360k(a). In light of this Court's recent decision in

(continued...)

REASONS FOR GRANTING THE WRIT

A. This Court's Guidance Is Needed To Resolve A Deep Post-*Lohr* Division Among The Federal And State Appellate Courts .

The decision below illustrates a deep post-*Lohr* split in authority in two important and related respects. **First**, the decision below widens the division among the federal circuit courts and state courts of last resort on the issue that was determinative in the court below: whether the FDA's grant of PMA for a medical device triggers preemption of state-law damages claims alleging that a manufacturer did not properly design and manufacture the device and failed to warn of the device's inadequacies. Some courts, including the Eleventh Circuit, hold that PMA does not trigger preemption under

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[4](...continued)
Buckman Co. v. Plaintiffs' Legal Committee, 121 S. Ct. 1012 (2001), finding a similar claim impliedly preempted by the MDA, petitioners do not press that claim. *Buckman* decided only whether a claim of fraud-on-the-FDA was impliedly preempted. It did not address, let alone decide, the question presented here, as the Solicitor General explained in *Buckman*. Brief for the United States as Amicus Curiae in *Buckman Co. v. Plaintiffs' Legal Committee*, No. 98-1768, at 5 n.2, 10 n.4 (U.S. filed June 7, 2000) (petition stage); *see also id.* at 14 (noting that fraud-on-the-FDA "claim is quite peculiar. It is independent of any claim against the manufacturer of the device in question, and it apparently does not depend on any showing that the device was somehow defective, or falsely advertised, under state law"). As explained in Part C below, the United States' view is that the kinds of claims presented here are not preempted.

section 360k(a) and that, therefore, state-law damages actions alleging injuries caused by PMA devices are not preempted. Other courts agree with the Sixth Circuit that PMA does, in fact, trigger preemption. *Compare, e.g., Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999) (no preemption); *Weiland v. Telectronics Pacing Sys., Inc.*, 721 N.E.2d 1149 (Ill. 1999) (same), *with, e.g., Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997) (preemption), *cert. denied*, 523 U.S. 1020 (1998); *Fry v. Allergan Medical Optics*, 695 A.2d 511 (R.I.) (same), *cert. denied*, 522 U.S. 952 (1997). As explained below in Part B, petitioners believe that the no-preemption rulings are better reasoned because they are truer to the text and purpose of section 360k(a) as construed by this Court in *Lohr*. For present purposes, however, the salient point is that there is deep conflict on an important and recurring issue of federal law that is significant to medical device patients, the industry that makes those devices, and the federal agency that regulates those devices.

Second, the courts of appeals and the state appellate courts are divided in their application of the analytic framework set forth in *Lohr* for resolving express preemption questions under 21 U.S.C. 360k(a). As noted above, *Lohr* requires that, before preemption may occur, both the allegedly preemptive federal requirement and the allegedly preempted state-law requirement must be "specific" within the meaning of section 360k(a) and regulations promulgated thereunder. *See* 21 C.F.R. 808.1(d).

1. Looking first to the federal-law side of section 360k(a)'s preemption inquiry, *Lohr* held that, to have preemptive effect under 21 U.S.C. 360k(a), the federal requirement must be specific. Thus, a specific labeling requirement for a particular type of device might have preemptive effect (*see, e.g.*, 21 C.F.R. 801.430), in contrast to

the comprehensive, but general, good manufacturing and labeling regulations that the Court held did not have preemptive effect. 470 U.S. at 497-99. In his concurrence, Justice Breyer suggested that an example of this type of specific federal requirement would be an FDA rule that a particular hearing-aid component be built with two-inch wires. *See id.* at 504.

Although the FDA's criteria for PMA applications are general and do not require devices to be designed, manufactured, or labeled in any particular manner, the Sixth Circuit nonetheless held that the PMA process was a "specific" requirement as applied to the FDA's review of the 4004M lead. 18a-19a. *Accord, e.g.*, *Worthy v. Collagen Corp.*, 967 S.W.2d 360, 376 (Tex.), *cert. denied*, 524 U.S. 954 (1998); *Fry*, 695 A.2d at 516; *Green v. Dolsky*, 685 A.2d 110, 117 (Pa. 1996), *cert. denied*, 520 U.S. 1168 (1997); *Steele v. Collagen Corp.*, 63 Cal. Rptr. 879, 887-88 (Cal. App. 1997). But as the Sixth Circuit noted in discussing the Eleventh Circuit's ruling in *Goodlin* (17a-18a), other appellate and trial courts have come to the opposite conclusion, holding that the PMA process itself is not a specific requirement under *Medtronic*. *Goodlin*, 167 F.3d at 1373-77; *Weiland*, 721 N.E.2d at 1152-53; *Sowell v. Bausch & Lomb*, 656 N.Y.S.2d 16, 20-21 (N.Y. App. Div. 1997); *Walker v. Johnson & Johnson Vision Prods., Inc.*, 552 N.W. 2d 679, 684 (Mich. App. 1996); *Haidak v. Collagen Corp.*, 67 F. Supp.2d 21, 23-24 (D. Mass. 1999) (*Lohr* effectively overrules pre-*Lohr* First Circuit decision ascribing preemptive effect to PMA); *Lakie v. SmithKline Beecham*, 965 F. Supp. 49 (D.D.C. 1997); *Quillen v. American Hosp. Supply Corp.*, 1997 U.S. Dist. Lexis 6974, *14-*15 (N.D. Okla. Mar. 31, 1997).[5]

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[5]Similarly, two state Supreme Courts have held that (continued...)

2. The split in authority is also profound on the state-law side of *Lohr*'s preemption analysis. The Sixth Circuit simply ignored *Lohr*'s holding that damages claims are not preempted if they are premised on general state-law duties that do not focus specifically on medical devices. Other post-*Lohr* courts that have found preemption of damages claims have dealt with the issue more directly, acknowledging *Lohr*'s majority holding and noting that it would, if applied to the case at hand, require a ruling in favor of the plaintiff. *See, e.g., Papike v. Tambrands, Inc.*, 107 F.3d 737, 742 (9th Cir. 1997). Those courts have not followed this portion of the majority opinion on the ground that it is incompatible with Justice Breyer's concurrence. *Id.* at 742; *Mitchell*, 126 F.3d at 912; *Papike*, 107 F.3d at 742; *see also Steele v. Collagen Corp.*, 63

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[5](...continued)
state-law damages claims involving class III devices marketed under the MDA's investigational device approval process (*see* 21 U.S.C. 360j(g)) — which is often a precursor to the PMA process — are not preempted because that process does not establish specific requirements under *Medtronic*. *Connelly v. Iolab Corp.*, 927 S.W.2d 848 (Mo. 1996) (en banc), *cert. dismissed*, 520 U.S. 1260 (1997); *Niehoff v. Surgidev*, 950 S.W.2d 816, 822 (Ky. 1997). On the other hand, the principal reason given by the court of appeals below for according the PMA process preemptive effect was its prior decision in *Martin v. Telectronics Pacing Sys., Inc.*, 105 F.3d 1090, 1095 (6th Cir. 1997), *cert. denied*, 522 U.S. 1075 (1998), which held that the investigational device process does, in fact, establish preemptive federal requirements. *See* 18a; *see also Worthy*, 967 S.W.2d at 374 (noting conflict in appellate authority over preemptive effect of MDA's investigational device provisions and claiming that PMA and investigational processes are comparable).

Cal. Rptr. 879, 887 (Ct. App. 1997); *Fry*, 695 A.2d at 517. As discussed below (at 21), these appellate courts erred in applying (or, as in this case, disregarding) *Lohr*'s majority holding. On the question whether this Court should grant review, however, the significance of these rulings is that they are at odds with the decisions of other appellate courts that have held that this Court meant what it said in *Lohr*: State laws of general applicability are not among those laws targeted for preemption by section 360k(a).

For instance, in *Oja v. Howmedica*, 111 F.3d 782 (10th Cir. 1997), the plaintiff claimed that the defendant had failed to warn her about problems with a hip replacement device. The Tenth Circuit agreed with the defendant that there was at least one specific FDA-mandated warning that constituted a federal device "requirement" within the meaning of section 360k(a), but held that the plaintiff's failure-to-warn claim was not preempted because it was not based on a law relating specifically to medical devices:

> Like the failure to warn claim at issue in *Medtronic*, the general state common law requirements imposed by Oja's negligent failure to warn claim were not specifically developed "with respect to" medical devices. Instead, Oja's negligent failure to warn claim is predicated upon a general duty applicable to every manufacturer "to inform users and purchasers of potentially dangerous items of the risks involved in their use."

Id. at 789 (quoting *Lohr*, 470 U.S. at 501) (internal citations omitted). Other appellate courts have come to the same conclusion. *See Niehoff v. Surgidev*, 950 S.W.2d 816, 822 (Ky. 1997) (no preemption because "Kentucky's strict liability case law and statutes [on which plaintiff relies] are laws of general

applicability to all products and fall beyond the scope of the federal preemption under §360k"); *Walker*, 552 N.W.2d at 686 (same); *Mears v. Marshall*, 944 P.2d 984, 993-95 (Ore. App. 1997) (same), *review denied*, 961 P.2d 217 (Ore. 1998); *Wutzke v. Schwagler*, 940 P.2d 1386, 1391-92 (Wash. App. 1997) (same), *review denied*, 953 P.2d 96 (Wash. 1998); *Baird v. American Med. Optics*, 693 A.2d 904, 909-10 (N.J. Super., App. Div. 1997), *modified and remanded*, 713 A.2d 1019 (N.J. 1997); *Kernats v. Smith Indus. Med. Sys.*, 669 N.E.2d 1300, 1309 (Ill. App.) ("plaintiffs' claims emanate from general common-law duties and are not the sort of state requirements that section 360k was intended to preempt"), *appeal denied*, 675 N.E.2d 634 (Ill. 1996), *cert. denied*, 522 U.S. 1044 (1998); *Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763, 771-72 (Cal. App. 1996)(same), *review denied*, 1997 Cal. Lexis 833 (Feb. 19, 1997); *see also Quillen*, 1997 U.S. Dist. Lexis 6974, *17-*18 (same).

This Court should grant the petition to resolve these conflicts among the federal and state appellate courts.[6]

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[6]The split in authority is particularly troublesome in Illinois, where, if the complaint is filed in, or removed to, federal court, the plaintiffs' claims are preempted, *see Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997), *cert. denied*, 523 U.S. 1020 (1998), but if the complaint remains in state court, there is no preemption. *See Weiland v. Telectronics Pacing Sys., Inc.*, 721 N.E.2d 1149 (Ill. 1999). The same situation exists in Kentucky. *Compare* the decision below and in *Martin*, 105 F.3d 1090 (broad preemption holdings applicable to cases filed in federal courts in the Sixth Circuit), *with Niehoff*, 950 S.W.2d 816 (no-preemption ruling of Kentucky Supreme Court). A similar problem arises in

(continued...)

B. The Decision Below Cannot Be Reconciled With *Lohr*.

Review should also be granted because the Sixth Circuit's serious misinterpretation of *Lohr* leaves consumers injured by PMA devices without a damages remedy. In that regard, the court below erred in two fundamental ways.

First, the mere issuance of PMA is not a specific preemption-triggering requirement under section 360k(a). Although the PMA process is often more rigorous than the marketing process at issue in *Lohr*, 518 U.S. at 478-79 (explaining differences); *see also Buckman Co. v. Plaintiffs' Legal Committee*, 121 S. Ct. 1012, 1015 (2001), it is no more "specific." Both processes apply to class III devices generally, and neither specifies how a product must be designed, manufactured, or labeled. As the Eleventh Circuit in *Goodlin* explained, although the PMA process "differs in significant ways from the 510k process at issue" in *Lohr*, 167 F.3d at 1374, the result regarding preemption is the same: "[B]ecause the [PMA] approval itself neither reveals nor imposes any ascertainable substantive prerequisite for approval that we could compare to a purportedly conflicting state requirement, the approval itself does not fit within section 360k(a)(1)'s demand for a specific federal requirement." *Id.* at 1376; *see also id.* at 1376-77 (FDA's "conditions of [PMA] approval" are generic and thus also not preemptive). Thus, the PMA process

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[6](...continued)
California, where the state's own appellate courts are in conflict. *Compare Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763 (Cal. App. 1996) (no preemption), *review denied*, 1997 Cal. Lexis 833 (Feb. 19, 1997), *with Steele v. Collagen Corp.*, 63 Cal. Rptr. 879 (Cal. App. 1997) (preemption).

contains no rules similar to the FDA's device-specific labeling rules (*see, e.g.*, 21 C.F.R. 801.420), or to the hypothetical FDA-required two-inch hearing-aid wire discussed in Justice Breyer's *Lohr* concurrence. *Lohr*, 470 U.S. at 504. Indeed, as the Solicitor General has noted, the PMA process itself does not impose specific federal "requirements" because the device's specifications originate with the manufacturer, not with the FDA. Brief for the United States as Amicus Curiae in *Smith Indus. Med. Sys., Inc. v. Kernats* ("United States Brief in *Kernats*"), No. 96-1405, at 16 (U.S. filed Dec. 10, 1997); *cf. American Airlines, Inc. v. Wolens*, 513 U.S. 219, 228-29 (1995).

Second, the decision below disregards *Lohr* in holding that petitioners' claims — and, therefore, all traditional damages claims involving a PMA device — are preempted, even though they are, without dispute, premised on state-law duties of general applicability. *See* 37a (referring to Ohio Revised Code § 2307.76, which sets forth general duty to warn under Ohio products liability law). Although the court of appeals purported to review *Lohr* carefully (11a-13a), the holding of the *Lohr* majority — that state laws of general applicability are not within section 360k(a)'s preemptive reach — is not even mentioned in the Sixth Circuit's opinion. *See Lohr*, 470 U.S. at 501-02; *see also* United States Brief in *Kernats*, at 17-18 (state-law claims regarding PMA devices premised on duties of general applicability not preempted under *Lohr*). Moreover, the court of appeals did not mention, let alone apply, the FDA's longstanding preemption regulation, 21 C.F.R. 808.1, even though it is directly applicable here. That regulation, which was accorded substantial weight in *Lohr*, 470 U.S. at 496; *see id.* at 505-06 (Breyer, J., concurring), provides that section 360k(a) "does not preempt State or local requirements of general applicability where the purpose of the requirement relates ... to other products in addition to devices ...." 21 C.F.R.

808.1(d)(1).[7]

In sum, review should be granted because the ruling below is at odds with this Court's decision in *Lohr*.

C. The Government's Position On The Question Presented Underscores The Need For Review.

More than three years ago, in *Smith Industries Medical Systems, Inc. v. Kernats*, No. 96-1405, the Solicitor General responded to this Court's request for advice on the same issue presented by this petition. The Solicitor General agreed with the position of the plaintiffs in that case, which is the same as that of the petitioners here: that FDA pre-market approval does not preempt state-law damages claims. United States Brief in *Kernats* at 14-18. The Solicitor General's brief explained why, in light of the decision in *Lohr* and applicable statutes and regulations, claims regarding PMA devices are consistent with FDA's mission as set forth by Congress in the MDA. *See id.* The Solicitor General also noted that "[t]he current division

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[7] Nor can the Sixth Circuit's failure to analyze the state-law side of section 360k(a)'s preemption analysis be squared with Justice Breyer's concurrence. Justice Breyer explained that a specific federal regulation demanding a two-inch hearing-aid wire would preempt a common-law claim premised on a specific state-law requirement for a one-inch wire. *Lohr*, 470 U.S. at 504 (Breyer, J., concurring). Petitioners' state-law damages claims, however, based on general Ohio law duties to properly design and manufacture a product and to warn of a product's inadequacies, do not present a specific state-law requirement of this kind, and thus not the kind of direct conflict that concerned Justice Breyer.

among the lower courts ... would normally provide a strong justification for this Court to grant review and definitively resolve the conflict." *Id.* at 18. He further explained, however, that this Court did not have jurisdiction because the state appellate court decision in *Kernats* was not final under 28 U.S.C. 1257. *Id.* at 10-14.[8] Since the Solicitor General's December 1997 filing in *Kernats*, the division among the lower courts, and thus the need for this Court's guidance, has become much more pronounced, because of the subsequent issuance of the no-preemption decisions of the Eleventh Circuit in *Goodlin* and the Illinois Supreme Court in *Weiland*, and the decision below, among others.

Recently, the United States has filed briefs in *Buckman Co. v. Plaintiffs' Legal Committee*, No. 98-1768. Those briefs took the position ultimately adopted by this Court — that the "fraud-on-the-FDA" claim alleged by the plaintiffs there was impliedly preempted by the MDA. However, the Solicitor General maintained that the fraud-on-the-FDA claim was not expressly preempted by section 360k(a) and specifically noted that the position taken by the United States in *Buckman* was consistent with the position it had taken in *Kernats*. Brief for the United States as Amicus Curiae in *Buckman Co. v. Plaintiffs' Legal Committee*, No. 98-1768, at 5 n.2, 9-12 & n.4 (U.S. filed June 7, 2000) (petition stage); Brief for United States as Amicus Curiae Supporting Petitioner in *Buckman Co.*

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[8] In *Kernats*, the Solicitor General also argued that the pendency of a proposed FDA interpretive rule regarding preemption provided another reason to deny review. *See id.* at 19-20. That proposed rule has since been withdrawn. *See* Brief for the United States as Amicus Curiae in *Buckman Co. v. Plaintiffs' Legal Committee*, No. 98-1768, at 5 n.2 (U.S. filed June 7, 2000) (petition stage).

v. Plaintiffs' Legal Committee, No. 98-1768, at 11-16 (U.S. filed Sept. 13, 2000) (merits stage).

The United States' position is relevant because this Court has often accorded weight to an agency's views concerning the preemptive scope of a statute that it is charged with implementing, both as expressed in agency regulations, *Lohr*, 518 U.S. at 496-97; *id.* at 505-05 (Breyer, J., concurring); *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 714-15 (1985), and as expressed in the form of an *amicus* brief filed in private litigation. *Geier v. American Honda Motor Co.*, 120 S. Ct. 1913, 1926 (2001); *American Airlines*, 513 U.S. at 232-34; *see also Auer v. Robbins*, 519 U.S. 452, 462 (1997) (deference to government's position expressed in *amicus* brief proper where position constitutes "fair and considered judgment"). The government's position is not dispositive on the merits, but, taken together with the FDA's narrowly tailored preemption regulations, *see* 21 C.F.R. 808.1(d)(1), it provides another compelling reason to grant review. Put simply, the decision below immunizes respondent from traditional state-law damages liability based on an interpretation of a federal statute that is flatly at odds with the government's interpretation of that statute. That situation should not persist without this Court's blessing.

CONCLUSION

For the reasons stated above, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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May 24, 2001

UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

ELIZABETH and CLIFFORD KEMP,
Plaintiffs-Appellants,

v.

MEDTRONIC, INC.,
Defendant-Appellee.

No. 99-3720

Appeal from the United States District Court
for the Southern District of Ohio at Cincinnati.
No. 97-00103—Sandra S. Beckwith, District Judge.

Argued: May 3, 2000

Decided and Filed: November 1, 2000

Before: MOORE and GILMAN, Circuit Judges;
McKEAGUE, District Judge.

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*The Honorable David W. McKeague, United States District Judge for the Western District of Michigan, sitting by designation.

COUNSEL

ARGUED: Gregory M. Utter, KEATING, MUETHING & KLEKAMP, Cincinnati, Ohio, for Appellants. Thomas M. Parker, ROETZEL & ANDRESS, Akron, Ohio, for Appellee. **ON BRIEF:** Gregory M. Utter, Louis Francis Gilligan, KEATING, MUETHING & KLEKAMP, Cincinnati, Ohio, for Appellants. Thomas M. Parker, Sanjay K. Varma, ROETZEL & ANDRESS, Akron, Ohio, Karen A. Carroll, ROETZEL & ANDRESS, Cincinnati, Ohio, for Appellee.

McKEAGUE, D. J., delivered the opinion of the court, in which GILMAN, J., joined. MOORE, J. (pp. 40-42), delivered a separate concurring opinion.

OPINION

DAVID W. McKEAGUE, District Judge. This appeal requires us to determine whether the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. §§ 360c *et seq.*, to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*, preempt plaintiffs' common law and products liability tort claims alleging negligence *per se*, fraud on the Food and Drug Administration ("FDA"), and failure to warn under Ohio law. The district court found plaintiffs' claims were either preempted by the MDA or failed to present a genuine issue of material fact, and awarded summary judgment to defendant-appellee Medtronic, Inc. ("Medtronic"). For the reasons set forth below, we affirm the judgment of the district court.

I. BACKGROUND

In late December 1991, plaintiff Elizabeth Kemp was admitted to the Bethesda North Hospital Emergency Room complaining of profound dizziness, weakness, and malaise.

Cardiac testing revealed complete atrioventricular block. In order to regulate Mrs. Kemp's heartbeat, on January 2, 1992, doctors surgically implanted a Model 4004M pacemaker and lead, manufactured by defendant Medtronic, Inc.

More than three years later, in June 1995, Mrs. Kemp began experiencing recurrent dizziness and fainting spells, attributable to the failure of her Model 4004M pacemaker lead to properly regulate her heartbeat. Then, on June 4, 1995, Mrs. Kemp fainted while in the garage of her home and fell to the concrete floor. As a result of her fall, she hit her head, and awoke suffering headaches, facial pain, and neck pain. It was later determined that these symptoms were caused by bilateral subdural hematomas. These blood clots required surgery to relieve the pressure in Mrs. Kemp's skull, and even after surgery she continued to experience loss of sight, speech, and cognitive and motor capability. Consequently, Mrs. Kemp spent some three months in and out of hospitals and rehabilitation, and she continues to suffer related disorders resulting from the injuries sustained in her fall.

A. Development of the Medtronic Model 4004M

At the center of this dispute is Medtronic's Model 4004M pacemaker lead, the device implanted in Mrs. Kemp. A pacemaker lead is a medical device, used in conjunction with a pulse generator (commonly referred to as a pacemaker), that is designed to monitor and correct rhythm irregularities in the human heart. Before a new pacemaker lead may be marketed and sold to the public, the manufacturer must first receive one of various forms of governmental clearance from the FDA. In 1982, the FDA granted Medtronic an investigational device exemption from the premarket approval ("PMA") process to permit clinical trials of the Model 4003, a predecessor to the Model 4004M. Following clinical trials, Medtronic submitted the Model 4003 to the FDA for a complete PMA review. After the FDA accepted, reviewed, and evaluated the PMA application, it was referred to a panel of experts. The panel specifically compared the performance of silicone and

polyurethane as insulating materials and concluded that both options should be available to physicians. The Model 4003 ultimately received PMA approval from the FDA on July 29, 1986.

Two years later, on July 18, 1988, Medtronic submitted a PMA Supplement to the FDA for the Model 4004, which proposed several significant modifications to the Model 4003. In addition to the Model 4003 specifications already approved by the FDA, the Model 4004 PMA Supplement addressed, among others, modifications incorporating the use of insulation made of pellethane 80A polyurethane.

On October 31, 1989, Medtronic filed a PMA Supplement application for the Model 4004M lead. A bipolar lead like the Model 4004M pacemaker lead consists of an inner conductor coil, outer conductor coil, inner insulation, and outer insulation. Should the inner insulation fail, the lead may short circuit, and fail to sense the heartbeat. If such a failure occurs, then the pacemaker cannot regulate the heartbeat properly, and arrhythmia or arrest may result. Medtronic manufactured the Model 4004M using pellethane 2326-80A as inner insulation material, and designed the 4004M lead to have inner and outer conductor coils with a platinum sputter barrier coating. Medtronic represented that the addition of the platinum sputter better prevented the coils from metal-ion oxidation, a degradative process observed in earlier pacemaker models employing polyurethane insulation (such as pellethane). In its 4004M PMA Supplement, Medtronic represented that the platinum sputter functioned as a barrier between the pellethane insulation and bodily fluids, preventing direct contact and avoiding metal-ion oxidation. The addition of this platinum sputter coating constituted a manufacturing and design change necessitating the filing of a PMA Supplement with the FDA.

The FDA approved the Model 4004M PMA Supplement on March 28, 1990. Thereafter, however, an FDA inspection revealed a significant risk of failure for the 4004M lead due to degradation of the polyurethane insulating material, and in

October 1993, Medtronic issued a Health and Safety Alert recalling some 74,000 Model 4004M leads.

B. Procedural Posture

On January 24, 1997, Elizabeth Kemp and her husband Clifford sued Medtronic, alleging ten common law and statutory products liability tort claims under Ohio law. Moving for summary judgment, Medtronic argued all of plaintiffs' state law claims were preempted by the express preemption provision of the MDA, § 360k. The United States District Court for the Southern District of Ohio largely agreed, finding the MDA preempted plaintiffs' strict products liability claims for defective design, failure to warn, and nonconformance to representations, as well as their claims for negligent design, negligent failure to warn, breach of express and implied warranties, and fraudulent misrepresentation with respect to medical devices approved through the FDA's premarket approval process. The district court did not find that the MDA totally preempted plaintiffs' claims, however, and ruled that any claims alleging the Model 4004M deviated from FDA specifications were not preempted. The district court then permitted plaintiffs to file an amended complaint to that effect.

Accordingly, on January 19, 1999, plaintiffs filed an eight-count amended complaint. Count I of the amended complaint alleges negligence *per se* for Medtronic's failure to manufacture the Model 4004M in accordance with the FDA standards and requirements imposed by the Model 4004M PMA Supplement. Count II alleges negligence *per se* for Medtronic's failure to (1) submit an engineering change order that varied the thickness and coverage of the platinum sputter coating; (2) provide Solution A test results to the FDA; and (3) provide canine biostability test results to the FDA as required by representations in the PMA Supplement. Counts III-VII allege claims that arise in the event Medtronic manufactured a product different from that approved by the FDA. Finally, Count VIII presents a derivative claim for loss

of consortium on behalf of plaintiff Clifford Kemp, which is entirely dependent upon his wife's claims.

On January 22, 1999, Medtronic moved for judgment on the pleadings on all counts of the amended complaint except Count I, arguing that plaintiffs' claims were preempted pursuant to the analysis in the district court's January 12, 1999 order. In a separate motion filed that same day, Medtronic moved for a judicial determination of the "specific federal requirements" applicable to the Model 4004M. Ruling from the bench at a pretrial hearing, the district court granted Medtronic's motion for judgment on the pleadings on Counts II, IV, V, VI, and VII of plaintiffs' amended complaint. The district court also granted Medtronic's motion for judgment on the pleadings on Count III of the amended complaint, except to the extent that it could be read to assert a claim for strict liability for a manufacturing defect.

Addressing Medtronic's motion to determine the specific requirements applicable to the Model 4004M, the district court reviewed the Model 4004M PMA Supplement and determined that the FDA approval process established six specific requirements. In determining the sixth requirement, the district court ruled:

> The sixth requirement is that there must be a protective barrier coat between the conductor coil and the insulation, which is composed of platinum sputtering. And that appears at Pages VI-52 and VI-61.
>
> There are other specifications within the PMA Supplement. I don't think they are relevant because for the most part they relate to the electrodes and the type of steroid to be emitted and things which are not at issue in this case.
>
> I would note that Paragraphs 57 through 60 of the amended complaint allege that platinum sputtering must be consistent. And the plaintiffs allege this requirement on the basis of Medtronic's description of the coil winding process and the post winding examination of the

> wires. But I do not see this as being a design specification.
>
> There are also allegations in Paragraph 135 that Medtronic changed the coverage and thickness requirements for the platinum sputtering. That is not a part of the PMA Supplement. The specifications regarding platinum sputtering in the PMA Supplement are very general, and it does not appear to me that the FDA required a particular level of platinum sputtering.

J.A. at 2941-42. The district court then struck paragraphs in the amended complaint alleging that Medtronic improperly altered the platinum sputter barrier, failed to provide Solution A and canine biostability test results, and failed to warn plaintiffs of defects in the Model 4004M learned after FDA approval of the 4004M PMA Supplement.

Plaintiffs' remaining claims in Counts I and III asserted negligence *per se* and strict liability, respectively, and alleged Medtronic failed to manufacture the Model 4004M according to FDA specifications. The final claim in Count VIII alleged a derivative loss of consortium claim on behalf of Clifford Kemp. Thereafter, Medtronic again moved for summary judgment, and the district court granted the motion in a written opinion dated April 30, 1999.

II. STANDARD OF REVIEW

This Court reviews a district court's grant of summary judgment de novo. *See Terry Barr Sales Agency, Inc. v. All-Lock Co., Inc.*, 96 F.3d 174, 178 (6th Cir. 1996). A motion for summary judgment should be granted "if the pleadings, deposition, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). On summary judgment, the Court views the facts and all inferences drawn therefrom in the light most favorable to the nonmoving party. *See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

III. ANALYSIS

This appeal presents fractious issues which have sharply divided the various circuit courts which have considered them: whether the express preemption provision of the MDA, § 360k, preempts state law tort causes of action for negligence, "fraud on the FDA," and failure to warn committed by a defendant manufacturer of a Class III device both prior and subsequent to having received FDA approval of a PMA Supplement.

In 1976, Congress enacted the Medical Device Amendments, which modified the Federal Food, Drug and Cosmetics Act to allow the FDA to regulate medical devices. The MDA divides medical devices into three categories, or classes. The most strict FDA regulation is reserved for Class III devices, defined as those which: (1) are to be used for supporting or sustaining human life or that are of substantial importance in preventing impairment of public health; or (2) present a potential unreasonable risk of illness or injury. *See* 21 U.S.C. § 360c(a)(1)(C)(ii)(I-II). To market a Class III device within the United States, the manufacturer must either submit its product to the FDA for premarket approval ("PMA process"), or qualify for one of two exceptions to this time-intensive regulatory review. The PMA process involves close scrutiny of the device by the FDA, and approval requires that the FDA conclude that it has received "reasonable assurances of [the device's] safety and effectiveness" from the manufacturer. *Id.* § 360c(a)(1)(C). To that end, manufacturers must provide the FDA with samples of the device, an outline of the device's components, a description of the manufacturing process, copies of the proposed labels, and various other information. *See* 21 C.F.R. § 814.20(b). The FDA then reviews such submissions for an average of 1200 hours before either approving or disapproving the device. *Id.* §§ 812.1-.150; *see also Mitchell v. Collagen Corp.*, 126 F.3d 903, 905 (7th Cir. 1997).

A manufacturer may also gain regulatory clearance for a Class III device through one of two exemptions from the

PMA process. First, the statute permits devices that are "substantially equivalent" to medical devices in existence in 1976 to be marketed and sold without PMA approval, in order not to stifle competition with technology existing at the time of the enactment of the MDA. *See* 21 U.S.C. § 360j(g)(1). This limited form of review is known as "premarket notification" or "the § 510(k) process," and averages only 20 hours of review as opposed to some 1200 hours in the PMA process. *See Martin v. Telectronic Pacing Sys.*, 105 F.3d 1090, 1095 (6th Cir. 1997); *Reeves v. Acromed Corp.*, 103 F.3d 442, 446 (5th Cir. 1997).

Second, devices representing innovative technology may be marketed under an investigational device exemption ("IDE"), an experimental regimen that allows for unapproved devices to be utilized in human trials. An IDE permits a manufacturer to market "a device that otherwise would be required to comply with a performance standard or to have premarket approval for the purpose of conducting investigations of that device." 21 C.F.R. § 812.1. Accordingly, a device operating under the IDE exemption need not comply with premarket approval requirements during the trial period. *See* 21 U.S.C. § 360j(g); 21 C.F.R. §§ 812-813.

Should a manufacturer merely propose to modify a Class III device that has already received approval pursuant to the PMA process, the manufacturer may submit a PMA Supplement rather than re-submitting the entire device for review. *See* 21 C.F.R. §§ 814.39, 814.80. The procedures applicable to a PMA Supplement are the same as those applicable to an original PMA, although the FDA only requires the manufacturer to provide that information necessary to support the proposed modifications. *See id.* § 814.3(g). If the FDA grants approval to a PMA application or a PMA Supplement, it does so subject to conditions described in a document entitled "Conditions of Approval." This three-page form (1) requires the manufacturer to submit proposed labeling of the device prior to marketing; (2) limits advertising to the FDA-approved labeling for the device; (3) specifies that "[b]efore making any change affecting the

safety or effectiveness of the device, [the manufacturer shall] submit a PMA Supplement for review and approval by FDA;" (4) requires the manufacturer to submit postapproval reports at one-year intervals from the date of FDA approval; and (5) requires the manufacturer to report any incidents of adverse reaction to, or known defect of, the approved device. Furthermore, the manufacturer must report to the FDA, "[a]ny significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that *could not* cause or contribute to death or serious injury but *are not* correctable by adjustments or other maintenance procedures described in the approved labeling." J.A. at 997-99 (emphasis in original).

IV. PREEMPTION PRINCIPLES

A. Express Preemption Under Section 360k

The Supremacy Clause of the United States Constitution provides that the "Laws of the United States . . . shall be the supreme Law of the Land." U.S. Const. art. VI, cl.2. Hence, "state law that conflicts with federal law is 'without effect.'" *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). Central to determining questions of preemption is divining Congress' intent. *Id.* at 517-18. In view of the historic importance of federalism in these areas, the states' police powers relating to public health and safety are not preempted by federal law unless Congress' intent to do so is clearly expressed. *See Hillsborough County, Florida v. Automated Medical Lab., Inc.*, 471 U.S. 707, 715 (1985). Moreover, where as here, Congress has included an express preemption provision in a statute, a court may not look beyond it to consider implied preemption. Rather, "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted." *Cipollone*, 505 U.S. at 517.

At the center of the instant dispute lies section 360k of the MDA, which expressly preempts certain state law requirements governing medical devices:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement–
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

B. *Medtronic, Inc. v. Lohr*

In *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the Supreme Court addressed the question whether the MDA preempts various common law tort claims. The device in *Lohr* had not undergone a PMA review, but had instead been approved pursuant to the "substantially equivalent" exception found in § 510(k). In a five to four decision, the Court held that none of the plaintiffs' common law tort claims were preempted by the MDA. *Lohr*, 518 U.S. at 501-02. Justice Stevens' plurality opinion was joined by Justices Kennedy, Souter, and Ginsburg. Justice O'Connor concurred in part and dissented in part, and her opinion was joined by the Chief Justice, and Justices Scalia and Thomas. Justice Breyer concurred in part and in the judgment, and joined five of the seven parts of Justice Stevens' opinion. Hence, the five sections of Justice Stevens' opinion in which Justice Breyer concurred (Sections I, II, III, V and VII) form the opinion of the Court in *Lohr*.

Because the MDA contains an express preemption provision, a majority of the Justices agreed that the issue devolved to determining the extent to which the MDA preempts a plaintiff's state law claims. *Id.* at 484. Furthermore, speaking for a majority of the Court in Part V, Justice Stevens concluded that the *Lohr* plaintiffs could maintain at least some state tort law actions for violations of

FDA regulations. *Id.* at 494-95. Proceeding from this point of initial agreement, however, the Justices' understanding diverged. Justice Stevens, writing for himself and three other Justices, rejected the defendant's assertion that § 360k preempts all common law suits because such claims always constitute "requirements." Stevens reasoned that the broad construction urged by defendant would "require far greater interference with state legal remedies, producing a serious intrusion into state sovereignty while simultaneously wiping out the possibility of remedy for the [plaintiffs'] alleged injuries." *Id.* at 488-89.

Justice Stevens' opinion found support in the plain language of § 360k. He reasoned that the use of the term "requirement," rather than the term "remedy," indicated that Congress intended to preempt "device-specific enactments of positive law by legislative or administrative bodies, not the application of general rules of common law by judges and juries." *Id.* at 487-88. Accordingly, the plurality concluded "that when Congress enacted § 360k, it was primarily concerned with the problem of specific, conflicting state statutes and regulations rather than the general duties enforced by common-law actions." *Id.* at 489.

Reaching the opposite conclusion, Justice O'Connor wrote an opinion joined by three other Justices in dissent. In their view, a common-law duty came within the meaning of the term "requirement" as used in § 360k because common law causes of action "operate to require manufacturers to comply with common-law duties." *Id.* at 510. (O'Connor, J., concurring in part and dissenting in part). Therefore, these four Justices would hold that a "fair reading" of the statute "indicates that state common-law claims are preempted . . . to the extent that their recognition would impose 'any requirement' different from, or in addition to, FDCA requirements applicable to the device." *Id.* at 512. In stark contrast to the Justices joining Justice Stevens' opinion, the O'Connor block did not believe that the state common law had to be "specific" to be preempted. Rather, under their reasoning, common-law claims were preempted if they

imposed obligations "different from, or in addition to," any requirement of federal law. *Id.* ("The statute makes no mention of a requirement of specificity, and there is no sound basis for determining that such a restriction on 'any requirement' exists.").

Justice Breyer, concurring in part and in the judgment, nevertheless explicitly agreed with Justice O'Connor's interpretation that certain common law causes of action could constitute state "requirements" that would conflict with federal "requirements" and thus be preempted. To hold otherwise would invite anomalous consequences, reasoned Justice Breyer, who set forth a hypothetical to illustrate his analysis:

> Imagine that, in respect to a particular hearing aid component, a federal MDA regulation requires a 2-inch wire, but a state agency regulation requires a 1-inch wire. If the federal law, embodied in the "2-inch" agency regulation, pre-empts the state "1-inch" agency regulation, why would it not similarly pre-empt a state-law tort action that premises liability upon the defendant manufacturer's failure to use a 1-inch wire (say, an award by a jury persuaded by expert testimony that the use of a more than 1-inch wire is negligent)? . . . .
>
> Consequently, I believe that ordinarily, insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action.

Id. at 504-05.

The various courts of appeals that have confronted issues of preemption arising under the MDA have struggled mightily with *Lohr's* language in the effort to discern its holding. Part V of Justice Stevens' opinion, however, in which Justice

Breyer concurred, provides helpful guidance.[1] First, both "[t]he ambiguity in the statute – and the congressional grant of authority to the agency on the matter contained within it – provide a 'sound basis' for giving substantial weight to the agency's view of the statute." *Id.* at 496. Second, in attempting to determine what common law duties constituted preempted "requirements," the Court took pains to explain that:

> it is impossible to ignore [the Act's] overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest . . . . The statute and regulations, therefore, require a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended pre-emptive scope of the statute and regulations.

Id. at 499.

Consequently, those circuit courts that have considered the question of the preemptive effect of § 360k of the MDA have translated *Lohr's* emphasis on the FDA regulations to focus on whether (1) the FDA has established specific counterpart regulations or other specific federal requirements; that are (2) applicable to a particular device; and thus (3) make state regulations different from, or in addition to, the specific FDA requirements. *See Mitchell*, 126 F.3d at 910; *accord In re Orthopedic Bone Screw Products Liability Litig.* 159 F.3d 817, 822 (3d Cir. 1998)("*Bone Screw I*"); *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1371 (11th Cir. 1999). However, state or local requirements that merely "affect

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[1] When no single rationale commands the agreement of five Justices of the Supreme Court, "the holding may be viewed as that position taken by those Members who concurred in the judgment on the narrowest grounds." *Marks v. United States*, 430 U.S. 188, 193 (1977). Hence, Justice Breyer's concurrence takes on heightened significance in interpreting *Lohr's* holding.

devices" are not preempted if such regulations are not "requirements applicable to a device" within the meaning of the MDA.

C. Specific Federal Requirements

Hence, as a threshold matter, we must first determine whether the FDA has established specific federal requirements applicable to the Model 4004M pacemaker through the PMA process. Plaintiffs draw our attention to the recent decision of the Eleventh Circuit Court of Appeals in *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999), which addressed this exact issue on nearly indistinguishable facts. In *Goodlin*, the Eleventh Circuit held that FDA approval of a PMA Supplement does not establish federal requirements specific to the device. Defendants flatly disagree, arguing that our decision in *Martin v. Telectronics Pacing Systems, Inc.*, 105 F.3d 1090 (6th Cir. 1997), holding that IDE approval constitutes specific federal requirements, applies *a fortiori* to the PMA process.

In *Martin*, we confronted the question whether common law and statutory tort claims brought under Ohio law were preempted by FDA approval for a Class III device granted under the IDE exemption. The plaintiff in *Martin* filed suit after her implant – an experimental device that combined the functions of a defibrillator, a cardioverter, and a pacemaker – malfunctioned. *See id.* at 1092. The plaintiff then brought five claims under Ohio tort law for the injuries that she suffered. In a unanimous opinion affirming the district court's grant of summary judgment to the defendant, this Court noted that, "unlike the general federal requirements discussed in *Medtronic*, the regulations governing investigational devices are essentially device specific." *Id.* at 1097. The *Martin* court further observed that "*there are no specific regulations governing pacemakers like the one at issue; however, the application and approval process under the IDE is device specific.*" *Id.* (emphasis added). Reasoning that the extensive review process undertaken by the FDA explored "the methods, facilities, and controls used for

manufacture of the device," *Martin* went on to affirm the district court's ruling that the plaintiff's manufacturing defect, design defect, inadequate warning, supplier liability and derivative spousal claims were preempted by § 360k. *Id.* With regard to the plaintiff's claim for nonconformance to express representations, *Martin* found the plaintiff waived the claim by failing to properly address the argument to the district court. *See id.* at 1100-01.

Defendant contends the same logic that guided this Court in *Martin* compels a finding that the FDA's approval of the PMA Supplement for the Model 4004M lead established device-specific requirements, because PMA Supplement approval (and the underlying PMA approval) is even more difficult to obtain than IDE approval. Vehemently disagreeing, plaintiffs cite *Goodlin* and argue the PMA Supplement application process generally, and the 4004M PMA Supplement process particularly, do not establish federal requirements specific to the device.[2] Because the Eleventh Circuit tackled the issue presented here on largely indistinguishable facts in *Goodlin*, and held none of the plaintiff's claims were preempted, we now consider the *Goodlin* analysis in relation to the instant case.

Like Elizabeth Kemp, Lisa Goodlin was implanted with a Medtronic Model 4004M pacemaker lead to regulate her heartbeat. Following receipt of the October 1992 Health and Safety Alert letter issued by Medtronic at the instigation of the FDA, Goodlin elected to have her pacemaker removed as a precaution. Although her pacemaker did not demonstrate

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[2] In an opinion predating the Supreme Court's 1996 decision in *Medtronic, Inc. v. Lohr*, a panel of the Ninth Circuit reversed a grant of summary judgment in favor of a defendant manufacturer of a Class III device that had undergone PMA approval. Focusing upon the regulations promulgated by the FDA, the Ninth Circuit opined that PMA approval does not constitute a "*specific* requirement applicable to a *particular* device" under 21 C.F.R. § 808.1(d), and held § 360k of the MDA does not preempt state common law tort claims of general applicability. *Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1459-60 (9th Cir. 1995) (emphasis in original).

any indication of failure, Goodlin brought suit against Medtronic claiming negligent design and strict products liability under Florida common law. The district court ruled the MDA preempted Goodlin's claims, because the FDA had approved the Model 4004M through the PMA process, and granted summary judgment to Medtronic. On appeal, a panel of the Eleventh Circuit reversed the judgment of the district court. *See Goodlin*, 167 F.3d at 1368-69.

Parsing the Supreme Court's decision in *Lohr*, the *Goodlin* court inquired whether "the FDA's PMA process, which produces a finding that the manufacturer has provided the reasonable assurances of safety and effectiveness necessary to market the device, translates into the necessary imposition of a 'specific requirement.'" *Id.* at 1375. After reviewing the PMA process, the *Goodlin* court concluded that PMA approval "represents only a finding that the manufacturer's proposal to market a device has reasonably assured the FDA of the device's safety and effectiveness" and that "[d]espite the specificity and considerable rigor of [PMA review] . . . neither the FDA's actual review of a device and its supporting information nor the agency's eventual approval of the device imposes any ascertainable requirement upon the device." *Id.*

In line with *Goodlin*, plaintiffs argue that in the absence of specific requirements, FDA approval of a PMA Supplement should not be granted preemptive effect. Plaintiffs further assert the issuance of a form approval letter setting forth generic "Conditions of Approval" does not mean that the FDA has established specific requirements applicable to the design and manufacture of the Model 4004M. Indeed, plaintiffs note that the FDA has never promulgated federal regulations regarding the manufacture of pacemaker leads. Plaintiffs also disagree that the FDA involvement in the PMA Supplement process is as involved as that in the IDE

application, and thus propose that the Court distinguish *Martin* on this rationale.[3]

We are not persuaded by plaintiffs' arguments, and respectfully disagree with the conclusions drawn by the panel of the Eleventh Circuit in *Goodlin*. Most importantly, *Goodlin*'s conception of what constitutes a "requirement" is irreconcilable with our analysis in *Martin* holding that IDE approval establishes specific federal requirements for the device in question. Although the IDE process imposes no "ascertainable substantive prerequisite for approval," this Court in *Martin* explained that the application and approval process under the IDE is a device-specific requirement that nevertheless has preemptive effect. *See Martin*, 105 F.3d at 1097. Our analysis comports with that advanced by the Seventh Circuit, which has held that "PMA approval by the FDA constitutes approval of the product's design, testing, intended use, manufacturing methods, performance standards and labeling" and is "specific to the product." *Mitchell*, 126 F.3d at 913; *accord Martin*, 105 F.3d at 1097.

Moreover, although the IDE process and the PMA process are not identical, a comparison of the governing regulations reveals no material differences.[4] Furthermore, the PMA

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[3]Plaintiff offers the affidavit of Charles H. Kyper, Director of the Premarket Approval Staff from 1981-1990. Kyper avers that:

> A PMA Supplement application is not reviewed with the same rigor as a PMA. Review of a PMA Supplement is much like a review of a 510(k) application in that both focus on the change being presented and assume the accuracy of information being presented and assume the accuracy of information presented in prior submissions. Typically, reviews of PMA Supplement applications are allocated 1/7th the time allocated for a PMA.

J.A. at 311.

[4]In fact, the *Martin* court found it significant that under the IDE process, the FDA required information regarding "the methods, facilities, and controls used for manufacture . . . of the device, in sufficient detail so that a person generally familiar with good manufacturing practices can

Supplement for the Model 4004M is composed of more than a hundred-page submission, and like the PMA, if the FDA ultimately grants approval to the modification in question, it means that the FDA has "received reasonable assurances of [the device's] safety and effectiveness." 51 Fed. Reg. at 26355. The FDA does not reach such a conclusion in approving a device pursuant to the IDE exemption, which by its very nature exists to permit experimental devices to be implanted to gather data in human trials. Hence, we agree with the district court's analysis that "preemption analysis regarding products approved through the PMA process is fully applicable to products approved through the PMA Supplement process." J.A. at 1369.

Plaintiffs further fail to adduce any evidence suggesting that a device approved pursuant to the PMA Supplement process, which builds upon the rigorous PMA process, receives any less scrutiny than does a device exempted from PMA approval under the IDE exemption process that was found to constitute specific requirements in *Martin*. Rather, plaintiffs' expert merely avers that a PMA Supplement is not reviewed with the same rigor as a PMA. This distinction is readily understandable because a PMA requires review of a previously unapproved device that does not qualify for exemption either as substantially equivalent to devices extant in 1976 or as an IDE. By contrast, a PMA Supplement proposes changes to a device that has already received rigorous review and approval during the original PMA

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make a knowledgeable judgment about the quality control used in the manufacture of the device." *Martin*, 105 F.3d at 1097 (quoting 21 C.F.R. § 812.20(b)(2)) (internal quotation marks omitted). Similarly, a PMA applicant is required to submit information regarding "[t]he methods used in, and the facilities and controls used for, the manufacture, processing, packing, storage, and, where appropriate, installation of the device, in sufficient detail so that a person generally familiar with current good manufacturing practice can make a knowledgeable judgment about the quality control used in the manufacture of the device." 21 C.F.R. § 814.20(b)(4)(v).

process. Hence, because the FDA has already made a determination as to the safety and effectiveness of the underlying device in the original PMA, it can evaluate only the proposed modifications presented in the PMA Supplement while relying on its earlier approval of the original device.

Finally, plaintiffs' argument that the FDA has never promulgated specific regulations governing pacemakers produces a result contrary to our understanding of *Lohr*'s holding. Under both plaintiffs' proposed analysis and under *Goodlin*, no cause of action involving any Class III device approved pursuant to the PMA process would ever be preempted because the FDA merely approves or disapproves the device in question, and does not set forth the basis for its decision. Hence, according to plaintiffs' position, preemption under § 360k would be exceedingly rare. Motivating Justice Breyer's refusal to join Part VI of Justice Stevens' opinion in *Lohr*, however, was his lack of conviction that "future incidents of MDA pre-emption of common-law claims will be 'few' or 'rare.'" *Lohr*, 518 U.S. at 508. (Breyer, J., concurring in part and concurring in the judgment). Indeed, we agree with Justice Breyer that, in enacting § 360k, Congress intended the preemption of some state-law causes of action, an intent given effect by this Court's *Martin* ruling. Following the logic of *Martin*, then, we hold that FDA approval of the Model 4004M PMA Supplement, taken together with the conditions of approval imposed on the device by the FDA, constitutes a specific federal requirement applicable to the device.

D. Specific Requirements Applicable to the Model 4004M

Having determined that the FDA's approval of the Model 4004M constitutes a specific requirement invoking preemption under § 360k, we must next determine what specific requirements are imposed by the FDA's approval of the Model 4004M PMA Supplement. Before the district court, the parties stipulated that the determination of the FDA

specifications applicable to the 4004M pacemaker lead was a matter of law for the court's determination. At a hearing on the issue, the district court ruled that six specifications were determined by the FDA during the PMA Supplement process for the 4004M lead.[5]

Although Medtronic does not appeal from the district court's decision, it argues on appeal that the FDA's "PMA approval" and the "Conditions of Approval," taken together, comprise the FDA's administrative response to Medtronics' PMA Supplement, establishing the specific federal requirements for the Model 4004M. As part of the PMA process, Medtronic submitted a detailed request for approval of a specific device of a particular design, using particular manufacturing processes and labels. Once approved, Medtronic concedes that the design, manufacturing processes, and labels may not be modified without further FDA approval, unless the modifications do not affect the device's safety or effectiveness. *See* 21 C.F.R. § 814.39. Thus, Medtronic argues it is the totality of the design, manufacturing processes, and labeling – when coupled with the prohibition against modifying them – that represents the specific federal requirement "applicable under [the MDA] to the device." 21 U.S.C. § 360k(a)(1).

We agree. The district court's attempt to parse the relevant requirements from Medtronic's PMA application and PMA

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[5]The district court identified six requirements that it believed were directly applicable to plaintiffs' claims, summarized as follows:
(1) The lead must have four polyurethane tines; (2) the conductor coils must be made of MP35N nickel alloy; (3) the lead must have polyurethane insulation; (4) the conductors must be constructed from MP35M nickel alloy, .005 inches in diameter and sputter coated with platinum; (5) the insulation must be made of 2363-80A polyurethane, of specified thicknesses; and, (6) there must be a protective barrier coat between the conductor coil and the insulation which is composed of platinum sputtering.
See J.A. at 2941-42.

Supplement, while an admirable effort to discern the relevant portions of the voluminous submissions to the FDA concerning the Model 4004M, does not comport with the actual PMA approval process that *Martin* (impliedly) and *Mitchell* (explicitly) relied upon to hold that the PMA process establishes specific federal requirements for a Class III device. It is true that in granting approval for a Class III device, the FDA does not set forth the reasons justifying its decision. Impliedly, however, the FDA has relied upon both the PMA submission approved for the original Class III device and the PMA Supplement providing specific information on the proposed modification in question. These specific submissions form the basis of the FDA's approval of the PMA Supplement. Thus, we conclude the specific requirements applicable to the Model 4004M include the entire relevant PMA and accompanying PMA Supplement, rather than certain portions thereof. In the case of the Model 4004M, then, the information submitted to and approved by the FDA in both the Model 4003 PMA and as modified by the Model 4004M PMA Supplement comprise the specific federal requirements applicable to Medtronic's Model 4004M pacemaker lead.

V. PLAINTIFFS' CLAIMS

A. Negligence Per Se

Having determined that the specific requirements for the Model 4004M are established by the July 15, 1988, Model 4004M PMA Supplement combined with the conditions of approval set forth by the FDA, we turn to take up plaintiffs' particular claims in light of the above analysis to determine whether they impose state-law requirements "different from, or in addition to," federal requirements. Counts I and II of plaintiffs' first amended complaint allege negligence *per se* for failure to comply with the FDA requirement to manufacture and sell the Model 4004M Pacemaker as FDA approved. In Count I, plaintiffs generally allege Medtronic failed to manufacture the Model 4004M as required by the

FDA and thus sold a misbranded and/or adulterated product. Count I further alleges that Medtronic's failure to manufacture the Model 4004M pacemaker lead as required by the FDA resulted in insulation failure, which proximately caused Mrs. Kemp's injuries.

Building on Count I, Count II alleges that Medtronic was required by the conditions of approval set forth in 21 C.F.R. § 814.84 to seek FDA approval for any change affecting the "safety and effectiveness of the device." Plaintiffs contend that Medtronic violated the conditions of approval for the Model 4004M pacemaker lead and 21 C.F.R. § 814.84 by failing to submit to the FDA a March 1989 deviation authorization and engineering change order concerning the coverage of platinum sputter coating over the conductor coils, by failing to provide results of canine biostability tests, and by failing to provide data from clinical devices or laboratory studies involving the 4004M.

Before the district court, plaintiffs elected to distill Counts I and II down, focusing solely on Medtronic's alleged failure to manufacture the Model 4004M pacemaker lead in conformance with the FDA-approved 4004M PMA Supplement specifications, and alleging that such failure constituted negligence *per se*. The essence of plaintiffs' argument is that Medtronic failed to coat the lead with a uniform 500 angstroms of platinum sputtering, resulting in the sale of a misbranded or adulterated product.[6] Before us, plaintiffs merely contend that under *Lohr*, a negligence *per se* claim survives any application of preemption under § 360k.

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[6] In their response to defendant's motion for summary judgment on March 9, 1999, plaintiffs characterized their claims as follows:

> Plaintiffs' negligence *per se* and strict liability claims focus solely on Medtronic's failure to manufacture the Model 4004M pacemaker with a "protective barrier coat of [sic] between the conductor coil and the insulation, which is composed of platinum sputtering."

J.A. at 2801.

To preempt these claims, the federal requirements must be "'applicable to the device' in question . . . and 'specific' to a 'particular device.'" *Lohr*, 518 U.S. at 500; *see also Martin*, 105 F.3d at 1098. To determine whether plaintiffs' negligence *per se* claims are preempted, however, we must first determine whether the specific requirements established by FDA approval of the Model 4004M PMA Supplement establish a requirement as to the required thickness and coverage of the platinum sputter barrier.

Addressing Count I, the district court granted summary judgment to Medtronic, ruling that any claim that the platinum sputtering may have failed to prevent insulation failure constitutes a claim for design defect, and is therefore preempted. The district court further ruled that neither the Model 4003 PMA nor the Model 4004M PMA Supplement required Medtronic to manufacture the Model 4004M lead with a particular thickness of platinum sputtering, and that if plaintiffs' common law claims asserted otherwise, they would constitute a requirement "different from, or in addition to," the non-specific federal requirement. Accordingly, such claims would be preempted. With respect to Count II, the district court granted defendant's motion for summary judgment on grounds of preemption, relying on our decision in *Bailey v. Johnson*, 48 F.3d 965, 968 (6th Cir. 1995), which held no private cause of action exists for a violation of the Federal Food, Drug and Cosmetics Act.

In support of the district court's judgment, Medtronic makes three arguments. First, Medtronic contends it manufactured the Model 4004M lead in conformance with FDA requirements. Second, Medtronic argues that under Ohio law, an action for negligence *per se* can only be predicated on a statutory violation. Third, Medtronic asks us to affirm on the ground that plaintiffs' negligence *per se* claims seek to circumvent the intent of Congress and should be preempted as impermissible attempts to create private causes of action for alleged violations of the Food, Drug and Cosmetics Act.

We agree with the result reached by the district court with respect to plaintiffs' negligence *per se* claims, yet we do so for different reasons. While we agree with plaintiffs that a claim premised on the violation of FDA requirements established for a Class III device through the PMA process is not automatically preempted, we nevertheless conclude that the district court properly granted summary judgment to Medtronic on plaintiffs' claims as presented, because we find that the specific federal requirements established by FDA approval of the Model 4004M PMA Supplement do not include a requirement as to the thickness or coverage of the platinum sputter barrier. To permit a jury to find Medtronic negligent for failing to manufacture the Model 4004M with a platinum sputter barrier of uniform 500 angstroms thickness would be to impose a requirement different from and in addition to those established by the FDA. It follows that plaintiffs' negligence *per se* claims are preempted.

Our review of the record leaves us firmly convinced that plaintiffs' argument that the Model 4004M PMA Supplement included a specification that the platinum sputter coat would be a uniform 500 angstroms thick represents at best a tenuous assertion and, at worst, an outright mischaracterization of the record. Both in their briefs and in oral argument, plaintiffs repeatedly asserted that the Model 4004M specifications, as originally designed, called for a platinum sputter barrier a "uniform 500 angstroms thick." Plaintiffs' statements find no support in the record. Indeed, we find that the record flatly contradicts plaintiffs' position. Instead of calling for a uniform thickness of 500 angstroms, the ECO (engineering change order) reveals that the original coating specification provided, "[c]oating thickness shall be 500 ± 200 angstroms," and that Medtronic modified the design to call for "100 to 1000 angstroms over a minimum of 85% of the wire circumference." J.A. at 993. Therefore the original specification was not for a uniform 500 angstroms as

plaintiffs repeatedly assert, but rather called for a range of 300 to 700 angstroms in thickness.[7]

Furthermore, nowhere in the Model 4004M PMA Supplement do we find that Medtronic made an express representation as to the thickness or coverage of the platinum sputter barrier. Apparently recognizing this glaring impediment to the success of their claims, plaintiffs nevertheless contend that Medtronic made binding representations as to the thickness of the platinum sputter barrier in submissions made to the FDA both prior and subsequent to the July 15, 1988 Model 4004M PMA Supplement.

First, plaintiffs contend Medtronic represented to the FDA that the thickness of the platinum sputter barrier would be 500 angstroms over 100% of the conductor coils in the premarket notification to the Model 4016A, a pacemaker not in the chain of development of the Model 4004M. Indeed, the Model 4016A was given FDA clearance pursuant to a § 510(k) premarket notification, rather than FDA approval pursuant to the PMA process. In answer to an FDA inquiry regarding the effect of platinum sputter on the weight distribution of the lead in the Model 4016A during its premarket notification process, Medtronic represented that because "the thickness of the platinum coating is only 500 Angstroms (Å), it is unlikely that it changes the weight distribution throughout the lead, thereby affecting electrode stability." *Id.* at 852. Plaintiffs next point to mathematical calculations that plaintiffs interpret as calling for 100% of the conductor coils to be sputtered at a thickness of 500 angstroms. Plaintiffs argue that these representations were incorporated into the Model

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[7] At oral argument, we explicitly asked plaintiffs to identify in the record what they contended established a thickness requirement for the platinum sputter barrier. In response, plaintiffs cited Medtronic's internal deviation authorization and engineering change order. J.A. at 986-90; 991-93. These pages do not contain any reference to the coverage of the barrier.

4004M PMA Supplement by Medtronic's statement in the Model 4004M PMA Supplement concerning the sputter barrier that, "[t]he Model 4016A pacing lead also incorporated these improvements." J.A. at 606.

We are utterly unconvinced that a statement in the Model 4004M PMA Supplement which merely points out that the addition of a platinum sputter barrier was incorporated in an earlier, unrelated model pacemaker is sufficient to establish a requirement for the Model 4004M. As a background consideration, the text from the Model 4004M PMA Supplement that plaintiffs claim incorporates the 4016A premarket notification is not placed in full context. After describing the modifications over the Model 4003, the Model 4004M PMA Supplement states in summation: "Therefore, two improvements incorporated into the Models 4004/4504 are: [b]arrier coating the conductor coils with platinum, and [t]hermal annealing tubing in an inert atmosphere (e.g., argon or nitrogen)." *Id.* at 605-06. The text goes on to state that "[t]he Model 4016A pacing lead also incorporated these improvements." *Id.* at 606. Combining these references, plaintiffs maintain they amount to a representation that the Model 4004M PMA Supplement incorporates all of the specifications submitted with the Model 4016A premarket notification.

Given the differences between the Model 4016A and the Model 4004M, plaintiffs' argument fails to persuade us. Underscoring the specious nature of plaintiffs' claim is the fact that the Model 4016A was merely judged substantially equivalent pursuant to the § 510(k) process, and was not reviewed and approved pursuant to the PMA process.[8] *Lohr*

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[8]Medtronic submitted its § 510(k) notification for its Model 4016A bipolar transvenous lead on September 28, 1987. The Model 4016A was a modification of the Model 4016 which was judged substantially equivalent to leads marketed prior to May 28, 1976, pursuant to the § 510(k) process on August 29, 1985. J.A. at 774.

rejected the notion that the § 510(k) approval process establishes specific federal requirements for a device. *Lohr*, 518 U.S. at 493. By contrast, the clear implication of the holding in *Martin* and the express import of our decision today is that FDA approval pursuant to a PMA Supplement establishes specific federal requirements for the device in question. Thus, we focus on the representations Medtronic made in the Model 4004M PMA Supplement which established its specific federal requirements to the exclusion of other submissions.[9] Accordingly, any representations made in the September 28, 1987, 4016A premarket notification, which did not receive FDA-approval, are inapplicable to the FDA-approved Model 4004M which received FDA approval after undergoing the PMA process.

The second submission plaintiffs rely on to establish a thickness requirement for the Model 4004M is the voluntarily withdrawn 1991 PMA Supplement for the Model 4003M.[10] On November 19, 1991, Medtronic submitted a PMA Supplement when it decided to modify the Model 4003M to incorporate a platinum sputter barrier.[11] In an attachment to this submission, Medtronic states, "[t]he sputtering process deposits only 500 angstroms of platinum on the conductor coil. Therefore, the physical properties of the coil are

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[9] Of course, the Model 4003 PMA, the ancestor of the Model 4004M, also established requirements applicable to the Model 4004M under our analysis, but any such requirements are not at issue here.

[10] Medtronic wrote to voluntarily withdraw its PMA Supplement for the Model 4003M on December 10, 1992, and the FDA acknowledged such withdrawal on December 18, 1992. *See* 21 C.F.R. § 814.44(g)(3); J.A. at 2877.

[11] The Medtronic Model 4003M, as PMA-approved on June 23, 1989, is a unipolar polyurethane pacing lead with a conductor coil that was not barrier coated. Medtronic submitted a PMA Supplement specifying the addition of a barrier coat of platinum sputter on November 19, 1991. J.A. at 2883.

virtually unchanged i.e., dimensions, flexural and electrical properties. Therefore, the performance of the leads will not change as a result of this sputtering process." J.A. at 2886. Based on this language, included in a withdrawn application, plaintiffs contend Medtronic represented that the thickness of the platinum sputter barrier for the Model 4004M pacemaker lead was a uniform 500 angstroms.

Again, plaintiffs rely on statements that are inapplicable to the Class III device in question, the Model 4004M. Most significantly, the Model 4003M PMA Supplement was voluntarily withdrawn by Medtronic, and thus never received FDA approval necessary to establish federal requirements. As we held in Part IV(d), *supra*, it is the PMA Supplement, coupled with the conditions of approval set forth in the FDA's approval letter, that establishes the specific federal requirements for a Class III device. The PMA Supplement for the Model 4003M, a unipolar lead, cannot reasonably be deemed to establish the requirements for the Model 4004M, a bipolar lead. Furthermore, the Model 4003M was not in the Model 4004M's chain of development; rather, the proposed modification adding the platinum sputter was submitted in 1991, after the approval of the Model 4004M in 1988. Hence, any reference contained in the withdrawn Model 4003M PMA Supplement cannot serve to establish requirements applicable to the Model 4004M, established through its PMA Supplement.

Having carefully scrutinized the record, our initial observation is confirmed: Medtronic represented that the Model 4004M would contain a platinum sputter barrier, but did not represent that the barrier would have a particular thickness. The specific federal requirements established by FDA approval of the Model 4004M PMA Supplement thus contain a requirement that the Model 4004M have a barrier of platinum sputter, and a claim for negligence *per se* premised on the lack of such a barrier would not be preempted. As pled and argued by plaintiffs, however, Medtronic was negligent in failing to manufacture a product that had a platinum sputter

barrier with a uniform 500 angstroms in thickness. Because the specific federal requirements applicable to the Model 4004M contain no thickness requirement, a jury verdict in plaintiffs' favor on plaintiffs' negligence *per se* claims would amount to a state requirement "different from, or in addition to," the federal requirements. It follows that plaintiffs' negligence *per se* claims are preempted. Consequently, we affirm the judgment of the district court in regard to this issue.

B. Fraud on the FDA

Count VII of the original complaint is entitled "Fraudulent Misrepresentation," and alleges "Medtronic, through its uniform course of conduct in the advertising, promotion, and sale of the [Model 4004M] leads, knowingly and purposely represented to the consumers of the product and to the medical community that the leads were fit for their intended purposes, would function without defect, and were appropriate for use in persons with heart conditions requiring pacemakers."[12] J.A. at 42. In their brief, however, plaintiffs characterize this claim as "Fraud on the FDA," and argue the district court erred by relying on *Michael v. Shiley, Inc.*, 46 F.3d 1316 (3d Cir. 1995), and *Klein v. Biscup*, 673 N.E.2d 225 (Ohio Ct. App. 1996), to find this claim was preempted by federal law.[13] As argued, plaintiffs' claim is similar to the fraud on the FDA claim presented to a panel of the Third Circuit in *In re Orthopedic Bone Screw Product Liability*

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[12] Plaintiffs' original complaint thus alleges that Medtronic fraudulently misrepresented the Model 4004M *to plaintiffs and their physicians*. As argued before the district court and on appeal, however, plaintiffs purport to have claimed that Medtronic fraudulently obtained FDA approval by failing to submit Solution A test results, canine test results, and other laboratory data prior to receiving FDA approval.

[13] In its ruling, the district court expressly relied on both *Michael* and *Klein*, and also noted that our decision in *Bailey*, 48 F.3d at 968, supported its conclusion that state-law claims for fraud on the FDA are preempted. J.A. at 1370-71.

Litig., 159 F.3d 817, 821-22 (3d Cir. 1998)(*Bone Screw I*), *cert. granted*, No. 98-1768 (U.S. June 29, 2000), which concluded that "*Lohr* overrules everything in *Michael* that would prevent a plaintiff from pursuing a cause of action for fraudulent misrepresentation based on common law principles." *Bone Screw I*, 159 F.3d at 825 (footnote omitted). Similarly, plaintiffs cite *Dutton v. Acromed Corp.*, 691 N.E.2d 738, 742 (Ohio Ct. App. 1997), and argue that the district court's reliance on *Klein* is misplaced. *Dutton* held that *Klein* does not survive the Supreme Court's holding in *Lohr*, and concluded that the plaintiff's fraud on the FDA claim was not preempted by the MDA.

Medtronic initially responds by arguing that Ohio law does not recognize a common-law cause of action for alleged fraud on a federal agency. Moreover, Medtronic contends that the district court properly extended our decision in *Martin* to find preemption. Medtronic rejects the holding of the Third Circuit in *Bone Screw I*, which it characterizes as a minority position adopted by no other circuit court, and urges us to hold with the Seventh Circuit in *Mitchell* that the earlier Third Circuit decision in *Michael* maintains its vitality even after the Supreme Court's decision in *Lohr*. Alternatively, Medtronic contends that the principle of implied conflict preemption dictates that we hold plaintiffs' fraud on the FDA claim to be preempted.

Under Ohio law, a claim of fraudulent misrepresentation requires a plaintiff to prove the following elements: "(a) a representation or, where there is a duty to disclose, concealment of a fact, (b) which is material to the transaction at hand, (c) made falsely, with knowledge of its falsity, or with such utter disregard and recklessness as to whether it is true or false that knowledge may be inferred, (d) with the intent of misleading another into relying upon it, (e) justifiable reliance upon the representation or concealment, and (f) a resulting injury proximately caused by the reliance." *Cohen v. Lamko, Inc.*, 462 N.E.2d 407, 409 (Ohio 1984) (per curiam). Once again, to preempt this

common-law claim, the federal requirements established by the Model 4004M PMA Supplement "must be 'applicable to the device' in question . . . and 'specific' to a 'particular device.'" *Martin*, 105 F.3d at 1098. (quoting *Lohr*, 518 U.S. at 500).

The issue presented here reaches to the heart of a sharp split between the various Courts of Appeals.[14] The Seventh Circuit has steadfastly, albeit tersely, maintained that claims alleging fraud committed through representations made to the FDA during the PMA process are preempted even after the Supreme Court's holding in *Lohr*. *See Mitchell*, 126 F.3d at 914 ("We continue to believe that this issue was decided correctly by the Third Circuit in *Michael v. Shiley, Inc.*"). In stark contrast, the Eleventh Circuit in *Goodlin* has held that no preemption of any state-law claims flows from FDA approval of a PMA Supplement, and the Third Circuit's decision in *Bone Screw I* held that state-law claims alleging fraud on the FDA are not foreclosed in light of the Supreme Court's decision in *Lohr*. *See Goodlin*, 167 F.3d 1381-82; *Bone Screw I*, 159 F.3d at 829. Recognizing the significance of the issue for thousands of plaintiffs across the country, the Supreme Court recently granted *certiorari*, limited to the following question: "Whether federal law preempts state-law tort claims alleging fraud on the Food and Drug Administration during the regulatory process for marketing clearance applicable to certain medical devices." *Buckman*

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[14] Count VII of plaintiffs' original complaint does not explicitly allege that Medtronic fraudulently obtained approval of the Model 4004M by presenting false information to the FDA. Rather, plaintiffs merely claim that Medtronic misrepresented the Model 4004M to plaintiffs and their physicians. To prove the falsity of Medtronic's representation as required under the third element of the claim, however, plaintiffs must establish that the Model 4004M was falsely represented to be safe and effective – the very determination made by the FDA in granting PMA approval. Consequently, although plaintiffs' Count VII claim does not expressly allege "fraud on the FDA," such a claim is necessarily implied in plaintiffs' allegations. .

Co. v. Plaintiffs' Legal Committee, *cert. granted*, No. 98-1768 (U.S. June 29, 2000).

We return to the language of *Lohr* to guide our determination whether a common-law claim for "fraud on the FDA" amounts to a state-law requirement, "different from, or in addition to," the specific federal requirements. Five Justices held in Part V of the *Lohr* decision that "[n]othing in § 360k denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Lohr*, 518 U.S. at 495. Hence, we must determine whether plaintiffs' claim alleging that Medtronic fraudulently obtained PMA Supplement approval from the FDA by failing to submit Solution A test results, by failing to perform canine studies, and by failing to submit laboratory tests for the Model 4004M, merely "parallels" federal requirements, or if, instead, it threatens to impose different or additional requirements, and thus is preempted.

Concluding that a requirement imposed by a cause of action for fraud on the FDA simply parallels federal requirements and thus is not preempted, the Third Circuit noted that 18 U.S.C. § 1001 makes it a crime to make a fraudulent statement to a federal agency, and that 21 C.F.R. § 807.87(j) requires every pre-market notification to contain a statement that the information contained therein is believed by the manufacturer to be truthful. *See Bone Screw I*, 159 F.3d at 823. Based on these two federal requirements, the *Bone Screw I* court concluded "the state common law relied upon [by the plaintiffs] does not impose any obligation on [defendant] inconsistent with federal law." *Id.*

Set against this analysis is the Third Circuit's holding in *Michael v. Shiley*, which the Seventh Circuit adopted after *Lohr* in *Mitchell v. Collagen Corp.* In its pre-*Lohr* decision, the *Michael* court held that permitting the plaintiff's claim for fraud on the FDA to go forward would impose a different requirement under state law, and thus was preempted by

§ 360k. First, and most significantly, the *Michael* court concluded that permitting the claim to go forward would open a pandora's box of judicial scrutiny of FDA decision-making, which "could ultimately require that a court determine whether the information [the defendant] submitted was truthful, whether it was complete, whether FDA procedures sufficed to avoid a material misrepresentation, and whether the FDA should have or would have approved the device despite the misrepresentations." *Michael*, 46 F.3d at 1329. In short, the *Michael* court feared that district courts would be required to adjudicate claims "applying state law, [and] to perform the same functions initially entrusted to the FDA." *Id.* Secondly, the *Michael* court reasoned that to permit a fraud claim based on allegedly false representations made by a manufacturer would conflict with longstanding precedent against permitting implied causes of action for violations of the Federal Food, Drug and Cosmetics Act.[15] *Id.*; *accord Bailey v. Johnson*, 48 F.3d 965, 966 (6th Cir. 1995). Expressly relying on this two-pronged analysis, a panel of the Seventh Circuit held the plaintiff's claims for fraud on the FDA were preempted in a tersely-worded ruling, stating its belief that *Michael*'s holding on this issue maintained its vitality even after the Supreme Court's ruling in *Lohr*. *See Mitchell*, 126 F.3d at 914.

Having carefully considered the question, we are convinced that the Third Circuit's analysis in *Michael*, adopted by the Seventh Circuit in *Mitchell*, correctly states the law and that nothing in *Lohr's* holding impairs *Michael's* reasoning. As a background consideration, we note that the plaintiffs in *Lohr* did not present a "fraud on the FDA" claim before the

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[15] This position has also been advanced by the Solicitor General for the United States as Amicus Curiae recommending the Supreme Court grant *certiorari* in *Buckman Co. v. Plaintiffs' Legal Committee*, *cert. granted*, No. 98-1768 (U.S. June 29, 2000) ("'fraud on the agency' claims could subject federal agencies to countless, highly intrusive inquiries into their internal deliberations").

Supreme Court. Furthermore, although tort claims for fraudulent misrepresentation have long been part of the common law, claims alleging fraud on federal agencies have never come within the "historic police powers of the States," a consideration that becomes relevant when determining the scope of preemption under §360k. *Lohr*, 518 U.S. at 495. It is one thing to note, as did the majority opinion in *Bone Screw I*, that federal law provides penalties for fraudulent statements made to government agencies. It is quite another to say that because federal law criminalizes such conduct, private litigants may bring a civil suit presenting a novel theory of liability under state common law to enforce an alleged violation of federal agency regulations. In our view, permitting plaintiffs to bring such actions does not equate to a "parallel" state law requirement as contemplated by *Lohr*; rather, such actions could conceivably impose both "different" and "additional" state law requirements in addition to the federal requirements specific to the Class III device established through the PMA process.

Initially, as noted by *Michael*, a jury presented with a common-law claim of fraud on the FDA might conclude that, but for the alleged misrepresentations made by the manufacturer, the FDA would have withheld approval of the device because it had not received reasonable assurance of the device's safety and effectiveness. To make such a showing, plaintiffs would have to adduce expert testimony from those familiar with FDA procedures, conduct discovery of FDA employees, and establish that the alleged misrepresentations rendered the device not safe and effective for its intended use. Effectively, actions for fraud on the FDA would allow individual juries to undertake a counterfactual FDA review, and conclude that the FDA would not have approved the device. However, "Congress allocated the FDA responsibility to design and manage a process which would result in approval of the safest and most effective medical devices possible. Congress also assigned the FDA the responsibility to approve or disapprove of applications to market medical devices." *Michael*, 46 F.3d at 1329. Furthermore, we agree

that permitting the "searching inquiry" of FDA internal procedures and personnel runs counter to both congressional intent and sound policy. Hence, we hold that to allow common-law suits for fraud on the FDA to go forward would permit juries to reach a different conclusion than the FDA did in approving the device in question, thereby imposing a different requirement than that required by the federal requirements. *Id.*

Finally, permitting a fraud claim premised on false representations to the FDA during the PMA process would conflict with well-established precedent that no implied private right of action exists under the FDCA. As we have previously observed:

> [T]he determination that a violation of a federal statute such as the FDCA will create state tort liability is not a matter solely of state law. A state's ability to use a federal statute violation as a basis for state tort liability and negligence per se depends on the intent of Congress, and not merely on the intent of the state. Thus, the congressional decision not to provide a private cause of action under the FDCA becomes quite important in considering the propriety of a state negligence per se action for violation of the FDCA.

In re Bendectin Litig., 857 F.2d 313-14 (6th Cir. 1988). Returning to answer this question when it was squarely before this Court, we held that no private cause of action exists for a violation of the FDCA. *See Bailey*, 48 F.3d at 967; *see also* 21 U.S.C. § 337(a) (restricting FDCA enforcement to suits by the United States); *accord In re Orthopedic Bone Screw Products Liability Litigation*, 193 F.3d 781, 788-89 (3d Cir. 1999); *PDK Lab., Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997); *Mylan Lab., Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993). States are not granted any authority to enforce compliance with the specific federal requirements established by the PMA process. Any common-law suit premised on allegations that Medtronic committed fraud on

the FDA and thus violated MDA amendments in its 4004M PMA Supplement submission conflicts with governing precedent in this circuit holding that no implied right of action exists for a violation of the Federal Food, Drug and Cosmetics Act. Plaintiffs cannot circumvent our prior decision by characterizing their claim as "fraud on the FDA," which we hold is preempted in accordance with the foregoing analysis.

C. Failure to Warn

Plaintiffs' inadequate warning claim is brought under Ohio Revised Code § 2307.76, which generally provides that a product is defective where the manufacturer fails to issue adequate warnings when the manufacturer knew, or reasonably should have known, of a risk of harm to the consumer. It is difficult to determine, however, the underlying basis of plaintiffs' claim as presented to the district court below. As set forth in their original complaint, Count IV is ambiguous: "At the time the Medtronic Models 4004 and 4004M leads were supplied to Plaintiffs, the products were defective as a result of Medtronic's failure to give adequate warnings, regarding polyurethane insulation, insulation failure, and lack of testing." J.A. at 39.

This statement could be read as asserting that the warnings found in the label and literature approved by the FDA for the Model 4004 and Model 4004M were inadequate under Ohio law. As noted above, however, the information submitted to and approved by the FDA in the Model 4004M PMA Supplement – including information regarding warnings and disclaimers – comprise the specific federal requirements applicable to defendant's pacemaker lead. Accordingly, to the extent that plaintiffs' claim is premised on the adequacy of the warnings reviewed and approved by the FDA, our analysis of the "fraud on the FDA" claim applies equally to the failure to warn claim, and the claim is similarly preempted. *See Martin*, 105 F.3d at 1100 ("To allow a state cause of action for inadequate warnings would impose

different requirements or requirements in addition to those required by federal regulations.").

The statement in Count IV could also be read, however, to assert a wholly separate and distinct claim that defendant acquired information subsequent to the FDA approval of the Model 4004M and before implantation of the device that would lead a reasonable manufacturer to warn patients and the medical community. Unfortunately, plaintiffs did not attempt to resolve this ambiguity until *after* the district court had already granted defendant summary judgment on the claim, in which the court clearly construed the claim – consistent with the parties' arguments – in accordance with the former understanding and not this latter, alternative meaning.

Because plaintiffs had ample opportunity to clarify this ambiguity – both in their original complaint and their brief in opposition to defendant's first motion for summary judgment – yet failed to do so in a timely manner, it is apparent that the claim they now argue on appeal was never properly presented to the district court and is not properly addressed by this Court in the first instance. Accordingly, we need not address the preemptive effect, if any, of § 360k on a claim for breach of a manufacturer's duty under state law to warn patients or the medical community of potential risks of a particular medical device based on information obtained subsequent to FDA approval of the device. Further, because of these pleading defects, we decline to remand this issue to the district court for further proceedings.

D. Derivative Spousal Claim

In light of the foregoing analysis finding that Elizabeth Kemp's claims are preempted by § 360k of the MDA, Clifford Kemp's derivative spousal claim is similarly preempted.

VI. CONCLUSION

For the foregoing reasons, we conclude that plaintiffs' claims are preempted and we **AFFIRM** the judgment of the district court. Defendant has not shown, however, good cause for continuing the seal on appellate briefs, and accordingly the seal is hereby **LIFTED**.

CONCURRENCE

KAREN NELSON MOORE, Circuit Judge, concurring. I agree with the majority that pursuant to our decision in *Martin v. Telectronics Pacing Systems, Inc.*, 105 F.3d 1090 (6th Cir. 1997), the FDA's approval of the Model 4004M PMA Supplement and the FDA's conditions of approval imposed on the 4004M pacemaker lead constitute a specific federal requirement, thereby triggering the possibility of preemption under 21 U.S.C. § 360k(a) of the Kemps' state law claims to the extent that the state law claims are different from or in addition to the federal requirements.

I also agree that the specific federal requirements established by the FDA approval of the Model 4004M do not include a requirement as to the thickness or coverage of the platinum sputter barrier. Because Mrs. Kemp's negligence claim is premised on a failure of the device to achieve a uniform thickness of the platinum sputter barrier, her negligence claim is preempted; a jury could not find in favor of Mrs. Kemp on the negligence claim without imposing a requirement "different from, or in addition to" the federal requirement. 21 U.S.C. § 360k(a)(1).

I agree as well with the more general principle stated by the majority that "a claim premised on the violation of FDA requirements established for a Class III device through the PMA process is not automatically preempted." Maj. Op. ante ¶ 70. Thus as the majority recognizes, a claim for negligence per se premised on the absence of a platinum sputter barrier as required by the FDA approval would not be preempted because the state claim would not impose requirements different from or additional to the federal requirements.

The claim that Medtronic committed a fraud on the FDA by improperly failing to submit certain tests and laboratory data

to the FDA during the approval process raises federalism concerns. Rather than force the analysis of this claim into the preemption framework of § 360k(a) and *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), I would instead focus on the peculiar nature of this claim. It appears from Kemp's appellate brief that she asserts that, because of alleged misrepresentations by Medtronic to the FDA, the FDA erroneously approved the 4004M, and she should therefore be able to recover damages on a state-law fraud claim. A determination in favor of Kemp on this fraud claim would effectively set aside the entire FDA approval process. Not only would litigants be able to explore and challenge the administrative decisionmaking process of the federal agency, but also conflicts could easily arise between the results of state-law fraud litigation and federal enforcement through federal civil and criminal penalties for false or misleading submissions to the FDA. *See, e.g.*, 21 U.S.C. §§ 331(q)(2), 333.

In any event, Kemp fails to point to any Ohio law upholding the viability of a "fraud against a federal agency" claim for damages to an individual user of a product. The case cited by Kemp, *Dutton v. Acromed Corp.*, 691 N.E.2d 738 (Ohio Ct. App. 1997), does not characterize the claim as a claim of fraud on the FDA but rather involves a claim of misrepresentation of a medical device's approval status to the affected individual. Such traditional fraud claims certainly are not preempted by § 360k(a) or by *Lohr*, which explained that "[n]othing in § 360k denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Lohr*, 518 U.S. at 495. Moreover, allowing a state fraud claim for misrepresentations made to the patient would not conflict with our decision in *Bailey v. Johnson*, 48 F.3d 965 (6th Cir. 1995), holding that the federal Food, Drug and Cosmetic Act does not impliedly provide a private *federal* cause of action for a violation of its provisions, since that state fraud claim would be premised on using the federal law as a behavioral standard as endorsed by the Supreme Court in *Lohr*. Kemp's

fatal problem is that her fraud claim on appeal is solely presented as a claim of fraud on the FDA rather than fraudulent misrepresentations to her.

In sum, I disagree with the majority's theory regarding the claim of fraud on the FDA but agree nonetheless with the conclusion that that claim must be dismissed. I agree with the conclusion that the negligence per se claim raised by Kemp is preempted because of the particular nature of her claim. I agree that we need not address the issue of whether § 360k preempts a claim of breach of a duty to warn patients of risks discovered after FDA approval of a device.

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

Elizabeth Kemp, *et al.*,

Plaintiffs,

vs.

Medtronic, Inc.,

Defendant.

Case No. C-1-97-103

Filed: January 12, 1999

ORDER

This matter is before the Court to consider Defendant Medtronic, Inc.'s Motion for Summary Judgment (Doc. No. 118) and Plaintiffs Elizabeth and Richard Kemp's Motion for Leave to File Surreply Memorandum (Doc. No. 146). For the reasons and analysis set forth below, the Defendant's motion for summary judgment is **GRANTED IN PART AND DENIED IN PART**; the Plaintiffs' motion to file a surreply memorandum is **MOOT.**

I. Background

The Plaintiffs in this case are Elizabeth Kemp and Richard Kemp. The Plaintiffs are citizens of the state of Ohio. The Defendant in this case is Medtronic, Inc. ("Medtronic").

Medtronic, a Minnesota corporation, manufactures and sells medical equipment and devices, including heart pacemakers and pacemaker leads. In January 1992, Elizabeth Kemp was implanted with a pacemaker that was manufactured with a Medtronic 4004M pacemaker lead ("the 4004M lead"). The 4004M lead is a Class III device under the federal Food, Drug, and Cosmetic Act.[1]

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[1] The FDCA provides the following definition of a Class III device:

> A device which because--
>
> (i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and (II) cannot be classified as a class II device because insufficient information exists to determine that the special controls described in subparagraph (B) would provide reasonable assurance of its safety and effectiveness, and
>
> (ii)(I) is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or (II) presents a potential unreasonable risk of illness or injury,
>
> is to be subject, in accordance with section 360e of this title, to premarket approval to provide reasonable assurance of its safety and effectiveness.

21 U.S.C. § 360c(1)(C).

On June 4, 1995, Mrs. Kemp fainted and hit her head on her concrete garage floor. Thereafter, Mrs. Kemp suffered from headaches, neck pain, and neck and facial swelling. On June 9, 1995, Mrs. Kemp underwent a cardiac telemetry which attributed the fainting episode to failure of the 4004M lead to operate properly. On June 10, 1995, Mrs. Kemp underwent surgery in which the 4004M was replaced with a new lead. The surgery required a three week hospital stay and an approximate two month stay in a nursing home for follow-up treatment. Because of the fall, Mrs. Kemp sustained a subdural hematoma which required a craniotomy and she has since been treated for two other hematomas.

The Plaintiffs initiated this products liability diversity action on January 24, 1997 with the filing of their Complaint (Doc. No. 1). In their Complaint, the Plaintiffs claim that Mrs. Kemp's injuries and resulting damages were caused by the failure of the 4004M to operate properly. Count I of the Complaint states a claim under Ohio law for strict liability based on defective manufacture, design, and warning.[2] Count II of the Complaint claims that Medtronic negligently tested, manufactured, retailed, designed, wholesaled, and distributed the 4004M lead. Count III of the Complaint states a claim for negligence per se. Specifically, Count III alleges that Medtronic was negligent in failing to comply with certain standards promulgated by the Food and Drug Administration which relate to the design, testing, research, and marketing of medical devices. Count IV of the Complaint alleges that Medtronic failed to warn the Plaintiffs of dangerous risks involved in the use of the 4004M lead. Count V of the Complaint alleges that

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[2]Although not specifically cited in the Plaintiffs' Complaint, these claims are based on Ohio's strict products liability provisions, Ohio Revised Code § 2307.71, *et seq.*

Medtronic breach implied warranties of safety, merchantability, and fitness for intended use. Count VI of the Complaint alleges the Medtronic breached express warranties of safety, merchantability, and fitness for intended use. Count VII of the Complaint alleges that Medtronic fraudulently misrepresented to Mrs. Kemp's health care providers that the 4004M lead was safe for its intended use, thereby inducing them to use the 4004M lead instead of other then available leads. Counts VIII and IX of the Complaint state claims for intentional and negligent infliction of emotional distress. Count X of the Complaint states a claim for mental distress and anxiety based on fear of future product failure. Count XI of the Complaint states a claim on behalf of Mr. Kemp for loss of consortium.

On August 21, 1998, Medtronic filed its motion for summary judgment. In its motion, Medtronic argues that summary judgment in its favor is appropriate because the Plaintiffs' state law claims are preempted by federal law. The motion for summary judgment has been fully briefed and is now ripe for disposition.

II. The Summary Judgment Standard

Summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The evidence presented on a motion for summary judgment is construed in the light most favorable to the non-moving party, who is given the benefit of all favorable inferences that can be drawn therefrom. *United States v. Diebold, Inc.*, 369 U.S. 654, 8 L. Ed. 2d 176, 82 S. Ct. 993 (1962). "The mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly

supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986)(emphasis in original).

The Court will not grant summary judgment unless it is clear that a trial is unnecessary. The threshold inquiry to determine whether there is a need for trial is whether "there are any genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party." *Anderson*, 477 U.S. at 250. There is no issue for trial unless there is sufficient evidence favoring the non-moving party for a jury to return a verdict for that party. *Id.*

The fact that the weight of the evidence favors the moving party does not authorize a court to grant summary judgment. *Poller v. Columbia Broadcasting System, Inc.*, 368 U.S. 464, 472, 7 L. Ed. 2d 458, 82 S. Ct. 486 (1962). "[T]he issue of material fact required by Rule 56(c) ... to entitle a party to proceed to trial is not required to be resolved conclusively in favor of the party asserting its existence; rather, all that is required is that sufficient evidence supporting the claimed factual dispute be shown to require a jury or a judge to resolve the parties' differing versions of the truth at trial." *First National Bank v. Cities Service Co.*, 391 U.S. 253, 288-89, 20 L. Ed. 2d 569, 88 S. Ct. 1575 (1968).

Moreover, although summary judgment must be used with extreme caution since it operates to deny a litigant his day in court, *Smith v. Hudson*, 600 F.2d 60, 63 (6th Cir.), *cert. dismissed*, 444 U.S. 986 (1979), the United States Supreme Court has stated that the "[s]ummary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole, which are designed to 'secure the just, speedy and inexpensive

determination of every action.'" *Celotex Corp. v. Catrett*, 477 U.S. 317, 327, 91 L. Ed. 2d 265, 106 S. Ct. 2548 (1986). According to the Supreme Court, the standard for granting summary judgment mirrors the standard for a directed verdict, and thus summary judgment is appropriate if the moving party establishes that there is insufficient evidence favoring the non-moving party for a jury to return a verdict for that party. *Id.* at 323; *Anderson*, 477 U.S. at 250.

Accordingly, summary judgment is clearly proper "against a party who fails to make a showing sufficient to establish the existence of an element essential to the party's case and on which that party will bear the burden of proof at trial." *Celotex Corp.*, 477 U.S. at 322. Significantly, the Supreme Court also instructs that the "the plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion" against a party who fails to make that showing with significantly probative evidence. *Id.; Anderson*, 477 U.S. at 250. Rule 56(e) requires the non-moving party to go beyond the pleadings and designate "specific facts showing that there is a genuine issue for trial." *Id.*

Further, there is no express or implied requirement in Rule 56 that the moving party support its motion with affidavits or similar materials negating the opponent's claim. *Id.* Rule 56(a) and (b) provide that parties may move for summary judgment "with or without supporting affidavits." Accordingly, where the non-moving party will bear the burden of proof at trial on a dispositive issue, summary judgment may be appropriate based solely on the pleadings, depositions, answers to interrogatories, and admissions on file.

III. Analysis

Medtronic's claim that the Plaintiffs' state law claims are preempted by federal law is premised on § 521 of the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360k, to the Food, Drug, and Cosmetic Act which provides in part:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

The U.S. Supreme Court first addressed the preemptive scope of § 360k(a) in *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 135 L. Ed. 2d 700, 116 S. Ct. 2240 (1996). In *Medtronic*, the plaintiff claimed that a pacemaker lead manufactured by Medtronic was defective and caused her to suffer injuries. The lead at issue was a 4011 lead which Medtronic marketed under the "substantially equivalent" provisions of the MDA (also known as the "§ 510(k) process" in reference to the original section in the Food, Drug, and Cosmetics Act). *Id.* at 478, 480. Under the MDA, a Class III medical device normally must undergo the FDA's premarket approval ("PMA") process, a

process the Supreme Court described as "rigorous," before the manufacturer may place the device on the market. *Id.* at 477; 21 U.S.C. § 360e(d)(2). However, under the substantially equivalent provision, a manufacturer may obtain expedited approval of a Class III device if the device is substantially similar to one marketed prior to 1976. *Medtronic*, 518 U.S. at 478; 21 U.S.C. § 360e(b)(1)(B). Medtronic claimed that the plaintiff's state law negligence and strict liability claims were preempted by § 360k(a). *Medtronic*, 518 U.S. at 481.

The decision in *Medtronic* generated a plurality opinion. In *Martin v. Telectronics Pacing Sys., Inc.*, 105 F.3d 1090 (6th Cir. 1997), the Sixth Circuit aptly summarized the effect of the plurality's decision:

> In a five to four decision, the Court held that none of the plaintiffs' common law claims were preempted by the MDA. The plurality opinion was authored by Justice Stevens and was joined by Justices Kennedy, Souter, and Ginsburg. Justice Breyer wrote a separate opinion, concurring in part and concurring in the judgment, in which he joined in five of seven parts of Justice Stevens' opinion. Thus, the five sections joined by Justice Breyer (Sections I, II, III, V, and VII) constitute the opinion of the Court.
>
> In determining the extent to which the MDA preempts state common law claims, the Court first noted that, while § 360k(a) is an express preemption provision in the MDA, the scope of federal preemption under § 360k(a) is ambiguous. This ambiguity in addition to Congress' express grant of authority to the Food and Drug Administration ("FDA") to implement the MDA, in the Court's opinion, rendered the FDA's interpretation of the statute entitled to substantial

weight. According to FDA regulations:

> State or local regulations are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:
>
> (1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g. requirements such as general electric codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.
>
> (2) Section 521(a) does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

Based on this language, the Court concluded that the statutory and regulatory language mandate that preemption occur only when the state and federal requirements meet certain criteria. A state requirement must be "with respect to" a medical device and must be "different from, or in addition to" federal requirements. Moreover, the state requirement must relate "to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device." Finally, "[s]tate regulations of 'general applicability' are not preempted except where they have 'the effect of establishing a substantive requirement of a specific device.'" The federal requirement "must be 'applicable to the device' in question ... and preempt state law only if they are 'specific' to a 'particular device.'" The Court divided on whether state common law actions could ever be preempted by the MDA. Significantly, a majority of the Court held that such actions do impose "requirements" under the MDA and are therefore preempted when the other conditions, as aforementioned, are satisfied.

Regarding the specific claims brought by the Lohrs, the Court held that none of their claims were preempted. With respect to the defective design claim, the Court concluded that, because the device was approved pursuant to the § 510(k) process, the device was never reviewed for safety and efficacy. Thus, because the § 510(k) process did not impose a federal "requirement," the claim was not preempted. Regarding the manufacturing and labeling claims, the Court rejected Medtronic's argument that federal regulations governing the labeling and manufacture of all medical devices were federal "requirements." The Court rejected the argument because federal labeling and

> manufacturing regulations "reflect important but entirely generic concerns about device regulation generally, not the sort of concerns" contemplated by the preemption provision of the MDA. Furthermore, the state common law requirements were not specifically developed "with respect to" medical devices and were not "the kinds of requirements that... would impede... the implement[ation] and enforce[ment] [of] specific federal requirements." The state requirement regarding negligent manufacturing was simply "the general duty of every manufacturer to use due care to avoid foreseeable dangers in its products." Similarly, the "failure to warn claim is the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use." Thus, none of these state requirements were "with respect to" a medical device. Accordingly, none of the plaintiffs' claims were preempted.
>
> Lastly, the Court concluded that if further development of the record and the plaintiffs' theories of recovery revealed that the Lohrs' action included a claim that Medtronic failed to comply with FDA regulations, that claim would not be preempted because "nothing in § 360k denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements."

Id. at 1093-94 (internal citations omitted).

The Sixth Circuit decided the *Martin* case on remand in light of the Supreme Court's decision in *Medtronic*.[3] In *Martin*,

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[3]In the original proceedings, the Sixth Circuit affirmed the district court's grant of summary judgment in the

the plaintiffs brought claims against the manufacturer of a pacemaker for strict products liability under Ohio law. The pacemaker involved was on the market pursuant to FDA approval through the "investigational devices exemption" ("IDE") procedures. The IDE process is an exception to the PMA process promulgated to "encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use." *Id.* at 1095; 21 U.S.C. § 360j(g). "Although investigational devices are not subject to the rigorous PMA process, they are subject to a different set of complex and comprehensive regulations which set forth detailed procedures for determining whether investigational devices are safe and effective." *Id.* The Sixth Circuit noted that, whereas the federal requirements in *Medtronic* were general in nature, the regulations governing investigational devices are essentially device specific and that the IDE application and approval process is device specific. *Id.* at 1097. The Court then analyzed each of the plaintiffs' strict liability claims with respect to the standards set forth in *Medtronic*.

With respect to the plaintiffs' claim for manufacturing defect, preemption was a two-step process. First, there must be a federal requirement regarding manufacturing that is "applicable to the device in question and specific to a particular device." *Id.* at 1098 (internal quotes omitted). Second, there must be a state requirement with respect to a medical device which is "different from or in addition to federal requirements" and that relates to "the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device." *Id.* (internal quotes omitted). The Court noted that

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defendant's favor based on § 360k preemption. *See Martin v. Telectronics Pacing Sys., Inc.*, 70 F.3d 39 (6th Cir. 1995).

there is a federal requirement regarding the manufacture of medical devices: the FDA had promulgated rules regarding manufacturing adequacy for investigational devices and exempts them from its good manufacturing requirements. The Court was not sure whether the products liability statue was a state requirement "with respect to" a medical device or just one of general applicability. The Court found, however, that a state law imposing liability for a manufacturing defect where the FDA specifically exempted the manufacturer from its good manufacturing requirements would thwart the goal of the IDE exemption, which is to encourage the development of useful human devices. Therefore, the Court held that the plaintiffs' claim for manufacturing defect was preempted. *Id.* at 1099.

The plaintiffs' claim for design defect presented a somewhat different problem. With respect to this claim, the Court noted that in *Medtronic*, the FDA had never reviewed the device for safety and efficacy because it was approved through the § 510(k) process. The § 510(k) process did not impose a "federal requirement" and therefore, in *Medtronic*, there was no preemption. *Id.* In contrast, in *Martin*, the FDA weighed the risks and benefits of the device in accordance with its regulations, and, in approving the marketing of the device, determined that the benefits outweighed the risks. Under the Ohio statute, however, a jury could conclude that the device's risks outweighed its benefits, thereby imposing a requirement different from the federal requirement. *Id.* The Court then addressed whether the state requirement was developed "with respect" to medical devices, finding that it probably was not. However, the Court held that allowing a cause of action for design defect where the FDA had specifically approved the design would impede the implementation and enforcement of a specific federal requirement by imposing a state requirement different from or in addition to it. Therefore, the plaintiffs' claim for design defect was preempted by federal law. *Id.*

With respect to the plaintiffs' inadequate warning claim, the Court noted that, whereas in *Medtronic* the federal requirement reflected a generic concern about warnings, in this case, the FDA had promulgated a comprehensive scheme regarding the content of device-related warnings. Furthermore, the FDA had reviewed and approved the warning at issue in the case. Even though the state requirement, i.e., the products liability statute, was not specifically developed with respect to medical devices, like the state requirements regarding defective manufacture and design, allowing a state law claim for inadequate warning would impede the implementation and enforcement of the federal requirements. Therefore, the plaintiffs' claim for inadequate warning was preempted by federal law. *Id.* at 1099-1100.

The Court then addressed the plaintiff's claim for nonconformance to express representations. The Court noted that, like the plaintiff's claims for defective manufacture, design, and warning, express representations regarding investigational devices are subject to comprehensive FDA regulation. Therefore, a state law claim that the device failed to conform to an express representation would impose a requirement different from or in addition to the FDA requirement. Therefore, this claim was preempted as well. The Court noted, however, that under *Medtronic*, a claim that the manufacturer "did not comply with MDA regulations governing its device would not be preempted" and a remedy could be pursued in state court. *Id.* at 1100-01.

In this case, in contrast to *Martin*, the procedures involved in approving the 4004M lead were the PMA process, rather than the IDE process. In actuality, the 4004M lead evolved from the 4004 lead, which in turn evolved from the 4003 lead. It is undisputed that the FDA approved the 4003 lead through the PMA process, and it is further undisputed that

the FDA approved both the 4004 lead and the 4004M lead through the PMA Supplement process. However, the first matter of business is to determine whether the PMA process establishes requirements that preempt state law. Of course the parties dispute whether that is in fact the case. The Court finds, however, that analysis of the PMA process generally parallels the Sixth Circuit's analysis of the IDE process in *Martin*. Therefore, with one exception, federal law preempts state law products liability claims where the FDA has approved a medical device through the PMA process. The second order of business, then, is to determine whether there is any meaningful difference between the PMA process and the PMA Supplement process so as to justify a finding that preemption principles that are applicable to the PMA process should not be applicable to the PMA Supplement process.

A. Defective Manufacture

In *Martin*, the Sixth Circuit found that the FDA specifically approves the manufacturing adequacy of an investigational device under 21 C.F.R. § 812.30(b)(5). *Martin*, 105 F.3d at 1098-99. 21 C.F.R. § 812.30(b)(5) provides:

> FDA may disapprove or withdraw approval of an application if FDA finds that ... [i]t is unreasonable to begin or to continue the investigation owing to the way in which the device is used or the inadequacy of ... [t]he methods, facilities, and controls used in the manufacturing, processing, packaging, storage, and, where appropriate, installation of the device[.]

21 C.F.R. § 812.30(b)(5)(ii)(1998). The FDA, however, exempts manufacturers of investigational devices from its good manufacturing regulations. Therefore, the Sixth Circuit held that allowing a claim for a manufacturing defect when the FDA

has exempted the manufacturer from complying with its good manufacturing regulations would thwart the goals of the IDE of encouraging the discovery and development of useful human devices. *Martin*, 105 F.3d at 1098-99.

FDA scrutiny of manufacturing adequacy in the PMA process is more exacting. For instance, the PMA application requires the manufacturer to provide a complete description of the "methods used in, and the facilities and controls used for, the manufacture, processing, packing, storage, and, where appropriate, installation of the device, in sufficient detail so that a person generally familiar with current good manufacturing practice can make a knowledgeable judgment about the quality control used in the manufacture of the device." 21 C.F.R. § 814.20(b)(4)(v)(1998). As a condition of approval of the PMA, the FDA may require an inspection that finds the applicant's manufacturing practices in compliance with the FDA's good manufacturing practices regulations. 21 C.F.R. § 814.44(e)(1)(ii) (1998). The FDA may deny approval of the PMA if the applicant's manufacturing processes do not comport with the FDA's good manufacturing practices regulations or if the applicant does not permit an FDA inspection of its facilities and controls. *See* 21 U.S.C. § § 360e(d)(2)(C), 360j(f); 21 C.F.R. § § 814.45(a), 814(a)(3) (1998). Thus, unlike an IDE medical device, a PMA medical device is not exempted from the good manufacturing regulations.

However, under Ohio law, a manufacturer is liable for a manufacturing defect when the product differs in a material way from its design specifications or from otherwise identical units. Ohio Rev. Code § 2307.74. Thus, under Ohio law, liability for a manufacturing defect does not hinge on whether the manufacturer failed to adhere to particular manufacturing standards. In reality, under Ohio law, a claim for manufacturing defect is the same as a claim, discussed further

infra at Part III.F.2., that the device actually manufactured differed in some way from the specifications approved by the FDA through the PMA process. Allowing a state law claim in this instance would not impose a state requirement different from or in addition to the federal requirement, it would only add state law reinforcement to the federal requirement.

Martin does not compel a different result. The *Martin* Court's rationale for finding preemption in that case was because the state law claim would thwart the federal interest in developing new products. Allowing a state law claim in this instance would not, however, thwart that interest. At this stage in the 4004M lead's development, it has passed the point where thwarting innovation is no longer a concern. As indicated by the applicability of the good manufacturing regulations, the federal interest here is in the quality of the process. However, as noted, liability does not hinge on the process, but rather on deviation from the specifications.

The Defendants note, however, that the Plaintiffs have not specifically plead in their Complaint that the 4004M lead deviated in a material way from its design specifications. Upon review of the Complaint, the Court finds that the Defendants are correct. On the other hand, as noted *infra*, Part III.F.2., with respect to the Plaintiffs' negligence per se claim, the Defendants do not specifically object to the Plaintiffs raising such a claim at this time. Therefore, the Court would direct the Plaintiffs to filed an amended complaint within 10 days which alleges that the 4004M lead deviated in a material way from its design specifications in violation of Ohio Revised Code § 2307.74.

B. Design Defect

In *Martin*, with respect to the plaintiff's claim for design defect, the Sixth Circuit found that in approving the IDE device, the FDA had balanced the risks and benefits of the device's design and had concluded that the benefits outweighed the risks. Allowing a jury to return a verdict that the risks of the device outweighed the benefits would be permitting a state requirement that is different from the federal requirement. *Martin*, 105 F.3d at 1099. Therefore, the claim for design defect was preempted.

The analysis is the same in this case. In the PMA process, in determining whether the device is safe and effective, the FDA considers "the probable benefit to health from the use of the device weighed against any probable injury of illness from such use[.] 21 C.F.R § 860.7(b)(3)(1998). The FDA determines that the device is safe when it can be determined that "the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks." 21 C.F.R. § 860.7(d)(1)(1998). Thus, like the IDE devices, in approving a device through the PMA, the FDA has determined that the benefits of the device outweigh the risks. Therefore, a jury verdict finding that the risks of a device approved through the PMA process outweighed its benefits would impose a state requirement different from the federal requirement. Therefore, a claim for design defect or negligent design would be preempted by the MDA.

C. Defective Warning

In *Martin*, the Sixth Circuit found that the FDA imposed specific requirements regarding warnings for IDE devices. Therefore, the plaintiffs' claims for inadequate warnings were

preempted because a state law cause of action would impose requirements in addition to or different from the federal requirements. Again, the analysis here parallels the *Martin* Court's analysis.

As a prescription medical device, the labeling on a pacemaker is required to bear information for use, "including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented[.]" 21 C.F.R. § 801.109(c) (1998). In the PMA application, the applicant must include copies of all proposed labeling for the device. 21 C.F.R. § 814.20(b)(10)(1998). In determining whether the device is safe and effective, the FDA weighs the risks and benefits of the device in light of accompanying directions for use and warnings against unsafe use. 21 C.F.R. § § 860.7(d)(1) & (e)(1)(1998). Thus, in approving the PMA, the FDA has determined that the warnings for the device are adequate. Therefore, a state law claim for inadequate warning would be preempted because it would impose a requirement different from or in addition to the federal requirement.

D. Nonconformance to Express Representations

The *Martin* Court's preemption analysis with respect to the plaintiffs' claim for nonconformance to express representations was very similar to its analysis regarding the plaintiffs' claim for defective warning. The Court noted that the FDA regulates the contents of IDE device labels, prevents the commercialization and promotion of IDE devices, and requires the applicant to submit the labeling for approval. Thus,

a claim for nonconformance to express representations is preempted because it would impose a state requirement different from or in addition to the federal requirement. *Martin*, 105 F.3d at 1100-01.

The analysis is the same in this case. As noted in Part III.C., *supra*, the FDA requires manufacturers to include certain specific information in medical device labeling. 21 C.F.R. § 801.109 (1998). The FDA requires the PMA applicant to submit the proposed labeling for approval. 21 C.F.R. § 814.20(b)(10) (1998). The FDA determines whether the device is safe and effective in light of accompanying warnings. 21 C.F.R. § § 860.7(d)(1) & (e)(1) (1998). The FDA will deny a PMA if the labeling does not comport with its requirements. 21 C.F.R. § 814.45(a)(2)(1998). The FDA will only approve a PMA based on draft labeling if the deficiencies "concern editorial or certain minor deficiencies." 21 C.F.R. § 814.44(d)(1)(1998). While the FDA does not appear to prohibit commercialization or promotion of PMA devices as it does IDE devices, in light of the stringent regulation of PMA labeling, the Court must conclude that a state claim for failure to conform to express representations is preempted as well.

Summary

Notably absent from the Plaintiffs' brief is any detailed analysis of *Martin*. The Plaintiffs cite decisions from two other circuits which held that the PMA process does not preempt state law products liability claims. *See Oja v. Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997); *Kennedy v. Collagen*, 67 F.3d 1453 (9th Cir. 1996). Neither case provides much support for the Plaintiffs. The Ninth Circuit issued its opinion in *Kennedy* a little more than a year before the Sixth Circuit issued its decision in *Martin*. Yet, the Sixth Circuit did not refer to the *Kennedy* case once in the entire *Martin* opinion. Thus, it may

fairly be said that the Sixth Circuit implicitly rejected the Ninth Circuit's analysis. *Oja* is similarly inapposite. The *Oja* Court addressed application of *Medtronic* only with respect to the plaintiff's failure to warn claims, and thus, in this case, would not be helpful with respect to the Plaintiffs' claims regarding design, manufacture, and express representations. *See Oja*, 111 F.3d at 788-89. Furthermore, the *Oja* Court's application of *Medtronic* was opposite the *Martin* Court's application of *Medtronic* and indeed, the *Oja* Court distinguished *Martin* in its opinion. *See id.* at 787 n.2.

Accordingly, based on the foregoing analysis, the Court finds that federal law preempts state law strict products liability claims for defective design, warning, and nonconformance to representations, and claims for negligent design, negligent failure to warn, and breach of express and implied warranties, and fraudulent misrepresentation with respect to medical devices approved through the PMA process. Claims for strict liability for defective manufacture and negligent manufacture are preempted to the extent that the claims challenge the manufacturing process itself. However, such claims are not preempted where the claim alleges that the manufacture of the device deviated from FDA-approved specifications.

E. Whether the PMA Supplement Process Preempts State Law

It is undisputed that the 4004M lead at issue in this case was approved through the PMA Supplement process. The Plaintiffs argue that even if federal law preempts state products liability claims with respect to PMA medical devices, there is no preemption for products approved through the PMA Supplement process. The Plaintiffs' argument is without merit.

After obtaining PMA approval from the FDA for a medical device, a manufacturer must submit a PMA Supplement when it makes a change that affects the safety or effectiveness the device. 21 C.F.R. § 814.39(a) (1998). Instances where a PMA Supplement is required include but are not limited to: 1) new indications for use of the device; 2) labeling changes; 3) use of a different facility to manufacture, process, or package the device; 4) changes in sterilization procedures; 5) changes in packaging; 6) changes in performance or design specifications; and 7) extension of the expiration date of the device. 21 C.F.R. § § 814.39(a)(1)-(7) (1998). The PMA procedures are fully applicable to PMA Supplements but the applicant is only required to provide information that supports the change. 21 C.F.R. § 814.39(c) (1998). When questioned about its authority to accept and approve PMA supplements, the FDA stated:

> If the change affects the safety or effectiveness of the device, then the device, as changed, is a "new" device and under section 513(f) of the act is automatically classified into class III and subject to premarket approval. FDA could require that a new PMA be submitted for the device. In such circumstance, the new PMA would include information about the basic device, unnecessarily duplicating the original PMA, as well as new information about the effect of the change. FDA believes, however, that a PMA supplement will inform FDA of all safety and effectiveness issues attributable to the changes to the device. Moreover, FDA considers a PMA supplement and all the information in the PMA to be "before" the agency at the time the supplement is reviewed. Thus, when an applicant submits a PMA supplement for a change in an approved device, the applicant has, in effect, submitted a new PMA for the "new" (changed) device.

Premarket Approval of Devices, 51 F.R. 26342, 26354 (1986). Thus, the FDA wisely decided that if the original device is comprised of items A, B, C, and D, and the change only affects item D, it makes little sense to require the applicant to resubmit information about items A, B, and C. Therefore, the Court holds that its preemption analysis regarding products approved through the PMA process is fully applicable to products approved through the PMA Supplement process.

F. Remaining Issues

The Plaintiffs claim that Medtronic defrauded the FDA during the PMA application process by, *inter alia*, misrepresenting certain test results and violating certain other FDA regulations. Therefore, the Plaintiffs argue, their claims are not preempted. The Plaintiffs also contend that there is no preemption where the product the manufacturer builds is different from the design it submitted to the FDA for approval.

1. Fraud on the FDA

In their brief, the Plaintiffs cite a number of instances where Medtronic allegedly falsified or misrepresented the test results it reported to the FDA or otherwise violated FDA regulations in the PMA process. The Court notes that at least one circuit and one Ohio court of appeals have rejected claims of fraud on the FDA. *See Michael v. Shiley, Inc.*, 46 F.3d 1316 (3d Cir. 1995); *Klein v. Biscup*, 109 Ohio App. 3d 855, 673 N.E.2d 225 (Ohio Ct. App. 1996). The *Michael* Court rejected a claim of fraud on the FDA because it would place the court in the position of having to carry out functions assigned to the FDA, as well as conflict with its earlier decision that there is no implied cause of action for violations of FDA regulations. *See Michael*, 46 F.3d at 1328-29. Therefore, this type of claim is preempted, even if the manufacturer knowingly misled the

FDA. *Id.* at 1329. The *Klein* Court rejected a similar claim because the FDA is in the best position to determine whether the manufacturer withheld crucial information and assess the appropriate sanctions. Allowing a jury or court to second-guess the FDA's enforcement of its policies would conflict with Congress' intent to eliminate attempts by states to impose conflicting requirements on medical device manufacturers. *Klein*, 673 N.E.2d at 230.

The Court notes that Congress has provided extensive criminal and civil penalties for violating FDA regulations, including penalties for intent to defraud or mislead. *See* 21 U.S.C. § 331, 333. Additionally, the FDA has promulgated a comprehensive hearing scheme for the assessment of civil penalties. *See* 21 C.F.R § 17.1, *et seq.* (1998). The Court further notes that like the Third Circuit, the Sixth Circuit has held that there is no private cause of action for an FDA violation. *Bailey v. Johnson*, 48 F.3d 965, 966, 968 (6th Cir. 1995). In light of these considerations, the Court adopts the analysis of both the *Michael* Court and the *Klein* Court and holds that state law claims for fraud on the FDA are preempted by federal law.

2. Building a Device that Differs from FDA Specifications

Finally, the Plaintiffs argue that there is no federal preemption where the device that the manufacturer builds is different from the device approved by the FDA. The Plaintiff's contention is correct. In *Medtronic*, the Supreme Court stated that "it is clear that the [plaintiffs'] allegations may include claims that Medtronic has, to the extent that they exist, violated FDA regulations." *Medtronic*, 518 U.S. at 495. In *Martin*, the Sixth Circuit stated, "As indicated by *Medtronic* and as conceded by defendant, a claim that Telectronics did not comply with MDA regulations governing its device would not

be preempted[.]" *Martin*, 105 F.3d at 1101. As stated more clearly by the Seventh Circuit, a claim for negligence despite adherence to FDA standards is preempted. A claim for negligent adherence to FDA standards imposed in the PMA is not preempted. *Mitchell v. Collagen Corp.*, 126 F.3d 902, 913 & 913 n.6 (7th Cir. 1997).

The Defendants concede the authority but note that the Plaintiffs have not asserted such a claim in their Complaint. The Plaintiffs apparently are trying to shoehorn this claim into the negligence per se claim alleged in Count III of the Complaint. However, the Plaintiffs' negligence per se claim alleges only that Medtronic failed to comport with the FDA's good manufacturing regulations in constructing the 4004M lead. *See* Complaint PP 22-25. As noted *supra*, there is no private right of action for such a claim. The Plaintiffs do not contend in their Complaint that Medtronic failed to comply with the PMA specifications approved for the 4004M device. On the other hand, Medtronic has not specifically objected to the Plaintiffs alleging such a claim at this time. Medtronic only states that should the Court permit the Plaintiffs to assert this claim it will need additional time to prepare for trial.

In light of the lack of a specific objection to the Plaintiffs asserting this claim at this time, the Court would direct the Plaintiffs to file an amended complaint which alleges that the 4004M lead at issue deviated from the specifications approved by the FDA in the PMA and PMA Supplement.

IV. Motion to File Surreply

In its reply brief, Medtronic referred to Judge Bertelsman's decision granting summary judgment in its favor in a companion case filed in the Eastern District of Kentucky, *Lyons v. Medtronic, Inc.*, Case No. CA-95-198. The Plaintiffs

now move to file a surreply in order to address Judge Bertelsman's order. However, in deciding this motion, the Court has not relied on Judge Bertelsman's order. Therefore, the Plaintiffs' motion to file a surreply is **MOOT**.

Conclusion

In light of the foregoing analysis, the Plaintiff's claims for strict liability for defective design, warning, and, failure to conform to representations, negligence and negligent misrepresentation, failure to warn, breach of implied and express warranties, and fraudulent misrepresentation are preempted by federal law. To the extent the Plaintiffs' manufacturing defect and negligent manufacturing claims challenge Medtronic's manufacturing process, those claims are preempted by federal law. To the extent that those claims allege that the 4004M deviated from FDA specifications, the claims are not preempted. Plaintiffs are hereby **ORDERED** to file an amended complaint alleging such a claim within 10 days of this Order. Therefore, Medtronic's motion for summary judgment with respect to Counts I and II of the Complaint is **GRANTED IN PART AND DENIED IN PART.** To the extent that Count III of the Complaint alleges that Medtronic failed to comply with the FDA's good manufacturing practices, Medtronic's motion for summary judgment is well-taken and is **GRANTED.** To the extent that Count III can be read to assert a claim that Medtronic failed to build the 4004M lead in compliance with the PMA and PMA supplement, Medtronic's motion for summary judgment is not well-taken and is **DENIED**. The Plaintiffs are hereby **ORDERED** to file an amended complaint alleging such a claim within 10 days of this Order. Medtronic's motion for summary judgment with respect to Counts IV, V, VI, and VII of the Complaint is well-taken and is **GRANTED**. Medtronic's motion for summary judgment with respect to the Plaintiffs' claims for intentional and

negligent infliction of emotional distress, fear of future product failure, and loss of consortium, contained in Counts VIII, IX, X, and XI of the Complaint is not well-taken and is **DENIED**. The Plaintiffs motion to file a surreply brief is **MOOT.**

IT IS SO ORDERED

Date January 12, 1999

Sandra S. Beckwith

United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

Elizabeth Kemp, *et al.*,

Plaintiffs,

vs.

Medtronic, Inc.,

Defendant.

Case No. C-1-97-103

Filed: April 30, 1999

ORDER

This matter is before the Court on cross-motions for summary judgment filed by the parties (Doc. Nos. 199 & 201) and Plaintiffs' Motion for Leave to File Motion for Reconsideration (Doc. No. 206). For the reasons and analysis that follow, Defendant Medtronic Inc.'s motion for summary judgment is well-taken and is **GRANTED;** Plaintiffs' motion for summary judgment and motion for leave to file motion for reconsideration are not well-taken and are **DENIED**.

I. Procedural Background

Plaintiffs Elizabeth and Richard Kemp initiated this products liability diversity action on September 24, 1997. In their original complaint, Plaintiffs claimed that a heart

pacemaker lead manufactured by Medtronic, Inc. ("Medtronic") and implanted in Mrs. Kemp failed, thereby causing injuries to her. Plaintiffs brought claims under Ohio law for strict products liability for defective manufacture, design, and warning, negligent design, manufacture, and distribution, failure to warn, breach of implied warranties of safety, merchantability, and fitness for intended use, breach of express warranties of safety, merchantability, and fitness for intended use, fraudulent misrepresentation, intentional and negligent infliction of emotional distress, fear of future product failure, and loss of consortium. Plaintiffs also asserted a claim for damages under the theory that Medtronic failed to comply with certain standards of the Food & Drug Administration ("FDA") in designing, testing, researching, and manufacturing the pacemaker lead.

Following a period of discovery, Medtronic filed a motion for summary judgment on the grounds that federal law preempted Plaintiffs, claims. On January 12, 1999, the Court issued an Order (Doc. No. 159) which granted in part and denied in part Medtronic's motion for summary judgment. In the Order, the Court ruled that claims based on defective design, warning, and non-conformance to representations were preempted by federal law. The Court further ruled that claims based on a fraud on the FDA theory were preempted by federal law. The Court, therefore, granted summary judgment in Medtronic's favor on those claims.

In their memorandum in opposition to Medtronic's motion for summary judgment, Plaintiffs argued that federal law does not preempt products liability claims based on a theory that manufacturer failed to build the medical device in conformance with the applicable FDA specifications. The Court agreed but noted that nowhere in their complaint did

Plaintiffs allege that the pacemaker lead implanted in Mrs. Kemp deviated from the approved specifications. However, since Medtronic had not specifically objected to Plaintiffs asserting such a claim, the Court directed Plaintiffs to file an amended complaint which alleged that claim.

Plaintiffs responded by filing an eight count Amended Complaint (Doc. No. 162) which in part set forth a number of claims based on theories which the Court had previously ruled were preempted. Therefore, at a pretrial hearing, the Court granted Medtronic's motion for judgment on the pleadings on Counts II, IV, V, VI, and VII of the Amended Complaint. Court also granted Medtronic's motion for judgment on the pleadings on Count III of the Amended Complaint, except to the extent that it could be read to assert a claim for strict liability for manufacturing defect. *See* Hearing Tr. (Doc No. 195) at 2. Additionally, the Court struck a number of paragraphs in the Amended Complaint which were not relevant to the manufacturing defect claims. *See id.* at 48. Thus, what remained after the Court's rulings were claims for negligence per se and strict liability in Counts I and III based on Medtronic's alleged failure to build the pacemaker lead in conformity with FDA specifications, and a derivative state law claim in Count VIII for loss of consortium.

The parties agreed that determination of the FDA specifications applicable to the pacemaker lead was a question of law for the Court. Therefore, at the same hearing, the Court ruled that the relevant specifications applicable to the pacemaker lead at issue were as follows:

1. the lead must have four polyurethane tines;

2. the conductor coils must be made of MP35N nickel alloy;

3. the lead must have polyurethane insulation;

4. the conductors must be constructed from MP35M nickel alloy, sputter coated with platinum, and .005 inches in diameter;

5. the insulation must be constructed from 2363-BOA polyurethane. The inner insulation must be .007 inches thick and the outer insulation must be .010 inches thick. The nominal outer insulation must be .010 inches thick with a minimum thickness of .008 inches. The inner insulation must have a nominal thickness of .007 inches with a minimum thickness o .005 inches; and,

6. there must be a protective barrier coat between the conductor coil and the insulation which is composed of platinum sputtering.

See id. at 46-47. Following the Court's ruling on the applicable specifications, the parties agreed that, rather than proceed to trial, it would be appropriate for Medtronic to file a dispositive motion on the issue of whether the pacemaker lead complied with the specifications as promulgated by the Court.

Medtronic filed its motion for summary judgment (Doc. No.199) on February 16, 1999. Thereafter, Plaintiffs were granted leave to file their own motion for summary judgment, which they did on February 16, 1999 as well. *See* Doc. No.201.

Plaintiffs also filed motion for leave to file a motion for reconsideration of the Court's January 12, 1999 Order on Medtronic's summary judgment motion and its February 1, 1999 rulings on the FDA specifications. *See* Doc. No.206. The motions have been fully briefed and are now ripe for disposition.

I. The Summary Judgment Motions

A. Standard of Review

Summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The evidence presented on a motion for summary judgment is construed in the light most favorable to the non-moving party, who is given the benefit of all favorable inferences that can be drawn therefrom. *United States v. Diebold, Inc.*, 369 U.S. 654 (1962). "The mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986) (emphasis in original).

The Court will not grant summary judgment unless it is clear that a trial is unnecessary. The threshold inquiry to determine whether there is a need for trial is whether "there are any genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party." *Anderson*, 477 U.S. at 250. There is no issue for trial unless there is sufficient evidence favoring the

non- moving party for a jury to return a verdict for that party. *Id.*

The fact that the weight of the evidence favors the moving party does not authorize a court to grant summary judgment. *Poller v. Columbia Broadcasting System, Inc.*, 368 U.S. 464, 472 (1962)." [T]he issue of material fact required by Rule 56(c) ...to entitle a party to proceed to trial is not required to be resolved conclusively in favor of the party asserting its existence; rather, all that is required is that sufficient evidence supporting the claimed factual dispute be shown to require a jury or a judge to resolve the parties' differing versions of the truth at trial." *First National Bank v. Cities Service Co.*, 391 U.S. 253, 288-89 (1968).

Moreover, although summary judgment must be used with extreme caution since it operates to deny a litigant his day in court, *Smith v. Hudson*, 600 F.2d 60, 63 (6th Cir.), *cert. dismissed*, 444 U.S. 986 (1979), the United States Supreme Court has stated that the "[s]ummary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole, which are designed to 'secure the just, speedy and inexpensive determination of every action.'" *Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (1986). According to the Supreme Court, the standard for granting summary judgment mirrors the standard for a directed verdict, and thus summary judgment is appropriate if the moving party establishes that there is insufficient evidence favoring the non-moving party for a jury to return a verdict for that party. *Id.* at 323; *Anderson*, 477 U.S. at 250.

Accordingly, summary judgment is clearly proper "against a party who fails to make a showing sufficient to

establish the existence of an element essential to the party's case and on which that party will bear the burden of proof at trial." *Celotex Corp.*, 477 U.S. at 322. Significantly, the Supreme Court also instructs that the "the plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion" against a party who fails to make that showing with significantly probative evidence. *Id.*; *Anderson*, 477 U.S. at 250. Rule 56{e) requires the non-moving party to go beyond the pleadings and designate "specific facts showing that there is a genuine issue for trial." *Id.*

Further, there is no express or implied requirement in Rule 56 that the moving party support its motion with affidavits or similar materials negating the opponent's claim. *Id.* Rule 56(a) and (b) provide that parties may move for summary judgment "with or without supporting affidavits." Accordingly, where the non-moving party will bear the burden of proof at trial on a dispositive issue, summary judgment may be appropriate based solely on the pleadings, depositions, answers to interrogatories, and admissions on file.

B. Analysis

Under Ohio law, a manufacturer is strictly liable for injuries caused by a product that was defectively manufactured. Ohio Rev. Code § 2307.73(A) (1). A product is defective in manufacture if:

> when it left the control of its manufacturer, it deviated in a material way from the design specifications, formula, or performance standards of the manufacturer,

> or from otherwise identical units manufactured to the same design specifications, formula, or performance standards. A product may be defective in manufacture or construction as described in this section even though its manufacturer exercised all possible care in its manufacture or construction.

Ohio Rev. Code § 2307.74. In order to prevail on a products liability claim, the plaintiff must demonstrate that: 1) there was a defect in the product manufactured and sold by the defendant; 2) the defect existed in the product at the time it left the hands of the defendant; and 3) that the defect was the actual and proximate cause of the plaintiff's injuries. *Bonacker v. H.J. Heinz Co.*, 676 N.E.2d 940, 942 (Ohio Ct. App. 1996) ; *Shaw v. Toyotomi America, Inc.*, 654 N.E.2d 1337, 1339 (Ohio Ct. App. 1995) .

Under general negligence principles, as part of the prima facie case, the plaintiff must demonstrate the existence and breach of some duty owed by the defendant to the plaintiff. Under a negligence per se theory, the promulgation of a statute or regulation sets forth the duty owed by the defendant to the plaintiff, thereby reducing the elements the plaintiff must prove in order to prevail. *Chambers v. St. Mary's School*, 697 N.E.2d 198, 201 (Ohio 1998). Thus, in this case, the duty owed to Plaintiffs by Medtronic was to build the pacemaker lead in conformity with the applicable FDA specifications, the breach of which duty would constitute negligence per se.[1]

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[1]The Court notes at this time that the Ohio Supreme Court held in *Chambers* that violation of an administrative rule does not constitute negligence per se. *See id.* at 203. Thus,

In support of its motion for summary judgment, Medtronic has submitted numerous internal quality control and inspection reports which indicate that the pacemaker lead which was implanted in Mrs. Kemp complied with the FDA specifications as promulgated by the Court. *See* Doc. No.199 Exs. 1A-IN. In their memorandum in opposition to Medtronic's motion for summary judgment, Plaintiffs concede that they are not claiming that the pacemaker was defective with respect to the first five specifications outlined by the Court. *See* Doc. No.204, at 1. Plaintiffs contend, however, that the pacemaker lead did not comply with the sixth specification in that did not have a protective barrier coating composed of platinum sputtering.

Plaintiffs' theory of the case is, and really has been, that the platinum sputtering on the pacemaker lead failed to prevent metal induced oxidation ("MIO"), which is the degradation of the insulation of the pacemaker lead caused by contact with bodily fluids. Plaintiffs contend that the pacemaker lead did not have a "protective barrier coating", and, therefore, was not built in conformity with the FDA specification, because it allegedly did not prevent MIO. As the Court pointed out at the February 1, 1999 hearing, however, the fact that the platinum sputtering may have failed to prevent MIO is a design defect, not a manufacturing defect, and claims for design defect are

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Medtronic argues, it cannot be held liable on a negligence per se theory for alleged failure to build the pacemaker lead in conformity with FDA specifications because the FDA specifications are administrative rules. Given the Court's ruling here today, however, the Court need not answer the question whether the FDA specifications are administrative rules so as to fall within the scope of *Chambers*.

preempted by federal law. *See* Hearing Tr. (Doc. No.195), at 69, 71. Plaintiffs could prevail on a manufacturing defect claim if it were shown that the lead did not have a coating of platinum sputtering. There is no dispute, however, that the pacemaker lead had a platinum sputter coating.

Plaintiffs also contend in their papers that Medtronic was required to coat the pacemaker lead with a 500 Angstrom thickness of platinum sputtering. As previously held by the Court, however, there is no specification in the PMA or PMA Supplement that required Medtronic to manufacture the lead with a particular thickness of platinum sputtering. Any claim based on such a theory would be a requirement "different than or in addition to" the FDA specification, and therefore, preempted. In their motion for reconsideration, Plaintiffs submit documents which they contend show that the FDA approved the lead design on the basis of a 500 Angstrom coating of platinum. A full reading of the documentation shows, however, that concern with a 500 Angstrom coating of platinum centered on whether such a coating affected the electrical performance of the lead, and not whether such a coating was necessary to prevent MIO. *See* Doc. No.206, Ex. 2B. Therefore, the Court could find that 500 Angstroms became a ***maximum*** requirement as to the electrical performance of the lead. Thus, had Mrs. Kemp's injuries allegedly been caused by a failure in the lead's electrical performance due to the thickness of the platinum sputtering, the Court could find that Plaintiffs would survive Medtronic's summary judgment motion. There is no support, however, for a claim that 500 Angstroms was a ***minimum*** requirement for prevention of MIO. Therefore, since it is not alleged that Mrs. Kemp's injuries were caused by a failure in the lead's electrical performance due to too much platinum sputtering, as a matter

of law, the alleged failure to coat the pacemaker lead with 500 Angstroms of platinum sputtering cannot be the cause of Mrs. Kemp's injuries.

Plaintiffs have not come forward with any evidence which contradicts the internal control documents of Medtronic that demonstrate that the pacemaker lead in question was manufactured according to the applicable specifications. Accordingly, Medtronic's motion for summary judgment with respect to Counts I and III of the Amended Complaint is well-taken and is **GRANTED**. Since the claim for loss of consortium in Count VIII of the Amended Complaint is derivative of Counts I and III, Medtronic's motion for summary judgment is well-taken and is **GRANTED** with respect to that claim as well. Plaintiffs' motion for summary judgment is not well-taken and is **DENIED**.

II. Motion for Reconsideration

In their motion for leave to file a motion for reconsideration, Plaintiffs ask the Court to revisit its earlier ruling that certain of their claims are preempted by federal law. Plaintiffs also ask the Court to revisit its ruling that the FDA specifications did not require Medtronic to coat the pacemaker lead with a specific amount of platinum sputtering.

In support of its motion for the Court to reconsider its preemption ruling, Plaintiffs rely on *Goodlin v. Medtronic. Inc.*, 167 F.3d 1367 (llth Cir. 1999), a case decided on February 18, 1999. In *Goodlin*, the Eleventh Circuit ruled that the PMA process does not preempt state law products liability claims because the Court could not discern any requirements imposed by the PMA process which would come in conflict with

requirements that might be imposed by a state law products liability claim. *See id.* at 1375-76. Beside the fact that the *Goodlin* decision does not bind this Court, its analysis is in conflict with the Sixth Circuit's analysis in *Martin v. Telectronics Pacing Systems, Inc.*, 105 F.3d 1090 (6th Cir. 1997), in which the Court held that state law claims for manufacturing and design defect, inadequate warning, and non-conformance to representations impose requirements different than or in addition to the FDA requirements. *See id.* at 1098-1101. Therefore, the Court declines Plaintiffs' invitation to review its earlier decision regarding preemption.

The Court also declines to reconsider its ruling on the specification regarding the thickness of the platinum sputtering. As the Court noted above, the documentation submitted by Plaintiffs in support of a requirement of 500 Angstroms of platinum sputtering deals with the electrical performance of the pacemaker lead and not prevention of MIO. Furthermore, even though the PMA does not specify a particular thickness of platinum sputtering, a claim based on a theory that Medtronic should have coated the pacemaker lead with a particular amount of platinum sputtering would be a requirement different from or in addition to the FDA requirement, and is, therefore, preempted.

Accordingly, the Court finds that Plaintiffs' motion for leave to file a motion for reconsideration is not well-taken and is **DENIED**.

Conclusion

In conclusion, Medtronic's motion for summary judgment is well-taken and is **GRANTED**; Plaintiffs' motion

for summary judgment and motion for leave to file a motion for reconsideration are not well-taken and are **DENIED**. Plaintiffs' remaining claims are **DISMISSED WITH PREJUDICE. THIS CASE IS CLOSED**.

IT IS SO ORDERED

April 30, 1999

Sandra S. Beckwith
United States District Judge

NOT RECOMMENDED FOR FULL-TEXT PUBLICATION

No. 99-3720

UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

ELIZABETH and CLIFFORD KEMP,

Plaintiffs-Appellants,

v.

MEDTRONIC, INC.,

Defendant-Appellee.

January 26, 2001, Filed

MEMORANDUM OPINION AND ORDER DENYING PETITION

Before: MOORE and GILMAN, Circuit Judges, McKEAGUE,* District Judge.

PER CURIAM. On November 1, 2000, this panel affirmed the judgment of the district court granting summary judgment to defendant appellee Medtronic, Inc.

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*Hon. David W. McKeague, United States District Judge for the Western District of Michigan, sitting by designation.

Plaintiffs-appellants filed a timely petition for rehearing with suggestion for rehearing en banc on November 14, 2000. We now take up the petition for rehearing.

Plaintiffs contend that we failed to address their negligence *per se* claims based on Medtronic's alleged violation of federal regulations and conditions of approval (for failure to submit additional Solution A and canine biostability testing to the Federal Food and Drug Administration ("FDA") during and after the PMA Supplement application process). We did address the Solution A and canine biostability testing allegations with respect to plaintiffs' "fraud on the FDA" claim. To the extent that plaintiffs would have the Court view the same allegations as having been asserted in support of "negligence *per se*" claims, we hold that the claims are not cognizable as such. There does not exist a *federal* private right of action for violation of the Federal Food, Drug and Cosmetics Act. *Bailey v. Johnson*, 48 F.3d 965, 966 (6th Cir. 1995). While a state may provide a right of action for violation of certain federal statutes and regulations, it appears that under Ohio law, the violation of administrative rules and regulations "does not constitute negligence per se." *Chambers v. St. Mary's School*, 697 N.E.2d 198, 203 (Ohio 1998) (holding that violation of a state administrative agency's regulations does not amount to negligence per se). Further, Ohio law provides that a claim for negligence per se may only arise when there exists a "positive and definite standard of care . . . whereby a jury may determine whether there has been a violation thereof by finding a single issue of fact." *Id.* at 201 (emphasis added). Plaintiffs have not identified, in their allegations or arguments, how Medtronics alleged failure to submit certain required test results to the FDA constitutes negligence *per se* -- i.e., the breach of a positive and definite duty of care owed to them, which breach proximately caused their injuries. Moreover, in any event, it is

clear that plaintiffs' claims involving Solution A testing and canine biostability testing implicate not a single issue, but multiple issues of contested facts. Accordingly, plaintiffs' "negligence *per se*" claims are not well-taken and were properly dismissed.

Furthermore, even if plaintiffs' claims were cognizable as negligence *per se* claims, considerations alluded to in our earlier majority and concurring opinions would militate overwhelmingly against remanding to the district court. As with their fraud claim, a determination in favor of plaintiffs on their negligence *per se* claims "would effectively set aside the entire FDA approval process," concurring slip op. at 41, permitting courts to "undertake a counter-factual FDA review, and conclude that the FDA would not have approved the device," majority slip op. at 35. We rejected plaintiffs' urging to permit this type of independent judicial review of federal agency decisions in our original opinion, and we reject it here as well.

Plaintiffs also ask us to reconsider our refusal to review an alternate theory of their duty to warn claim. We held that the claim actually asserted in the district court was preempted, and that an alternate theory had not been properly presented to the district court. Plaintiffs now charge that in reviewing their duty to warn claim, we "interpreted the ambiguity **against** plaintiffs, even though all inferences are to be drawn in favor of the non-movant when deciding summary judgment motions" (emphasis in original).

Plaintiffs are wrong. We did not construe any ambiguity against plaintiffs. Rather, we simply recognized that in addressing plaintiffs' failure to warn claim below, the district court reasonably interpreted the claim as an assertion that the

labels and literature specifically approved by the FDA did not adequately warn plaintiffs of certain risks. Pursuant to *Martin v. Telectronics Pacing Systems, Inc.*, 105 F.3d 1090 (6th Cir. 1997), *cert. denied*, 522 U.S. 1075, 139 L. Ed. 2d 751, 118 S. Ct. 850 (1998), such a claim is clearly preempted. Any alternate meaning that plaintiffs desire to ascribe to their failure to warn claim should have been clarified below in a timely manner. As explained in our earlier opinion, plaintiffs failed to do this. Accordingly, we properly declined to remand the issue to the district court for further proceedings.

Plaintiffs have failed to show that our original judgment was made in error. The petition for rehearing is therefore **DENIED**.

(2)

Supreme Court, U.S.
FILED
JUL 23 2001
OFFICE OF THE CLERK

No. 00-1766

In the Supreme Court of the United States

ELIZABETH KEMP AND CLIFFORD KEMP,

Petitioners,

v.

MEDTRONIC, INC.,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

The petition presents the question whether petitioners' state-law damages claims were preempted by 21 U.S.C. § 360k(a) on the ground that the Food and Drug Administration's grant of pre-market approval to Medtronic's 4004M pacemaker lead imposed specific federal requirements on that medical device. However, as we explain in this brief, that question is not in fact presented by this case.

RULE 29.6 STATEMENT

Respondent Medtronic, Inc. is a publicly traded corporation and has no corporate parent. No other publicly held company owns 10 percent or more of respondent's stock.

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United States Brief in *Smith Indus. Med. Sys., Inc.* v. *Kernats*, No. 96-1405, 118 S. Ct. 684 (1998) (Mem.) 27

BRIEF FOR THE RESPONDENT IN OPPOSITION

Petitioners assert that the Court should grant review here because *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), has caused confusion in the lower courts. However, this case, which was litigated below on grounds not presented in the petition, and which was decided by the Sixth Circuit consistently with both *Lohr* and the holdings of the great majority of lower courts, is not the vehicle in which to attempt to clarify the scope of preemption under Section 360k of the Medical Device Amendments (MDA), 21 U.S.C. § 360c *et seq.*, to the Food Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*

While the lower courts may be "sharply divided" in their interpretations of *Lohr* (Pet. 1, quoting Pet. App. 8a), the specific "sharp[] divide[s]" that the court of appeals referred to are not in fact presented in the petition; the first was decided below in part on state-law grounds, see Pet. 8 n.2; Pet. App. 84a, and the second was recently resolved by this Court in *Buckman Co.* v. *Plaintiffs' Legal Committee*, 121 S. Ct. 1012 (2001). The issues concocted for purposes of Supreme Court review do somewhat divide the lower courts, but those issues raise only academic questions in the context of this particular case.

STATEMENT

Tellingly, the petition provides almost no information about either the claims that petitioners actually raised below or about the pre-market approval ("PMA") process to which the specific medical device at issue was subjected. After briefly outlining the background legal structure applicable to preemption under the MDA, we set forth these critical facts.

A. The Regulatory Structure Of The Medical Device Amendments.

In 1976, Congress enacted the MDA, which vastly expanded the authority of the Food and Drug Administration (FDA) to regulate medical devices. At the same time that it established a comprehensive regulatory regime at the federal level, Congress sought to protect innovations in device technology from being "stifled by unnecessary restrictions." H.R. REP. No. 94-853, at 12 (1976). Specifically, Congress attempted to shield medical devices from the "undu[e] burden[]" imposed by differing state regulation by including in the MDA a "general prohibition on non-Federal regulation." *Id.* at 45. That general prohibition, which also serves to safeguard the uniformity of the federal regulatory scheme, broadly provides that no State may impose "any requirement" relating to the safety or effectiveness of a medical device that "is different from, or in addition to, any requirement applicable * * * to the device" under federal law. 21 U.S.C. § 360k(a).

This Court has twice considered the preemptive scope of the MDA — in *Lohr* and, more recently, in *Buckman*. In a fractured opinion, the *Lohr* Court held that the MDA's express preemption clause did not bar state-law tort actions challenging the design, manufacture, or labeling of "Class III" devices (those that either (1) are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or (2) "present[] a potential unreasonable risk of illness or injury," *id.* § 360c(a)(1)(C)), if those devices had been approved for sale through a simple "pre-market notification" under the "510(k)" process as the "substantial[] equivalent" of a device in existence before the passage of the MDA. See *Lohr*, 518 U.S. at 492-493.

The *Lohr* Court explicitly differentiated 510(k) approval of a device, which all members of the Court found not to pre-

empt at least certain state-law tort claims, from the PMA process for new devices, at issue in this case:

> Before a new Class III device may be introduced to the market, the manufacturer must provide the FDA with a "reasonable assurance" that the device is both safe and effective. See 21 U.S.C. § 360e(d)(2). Despite its relatively innocuous phrasing, the process of establishing this "reasonable assurance" [in the PMA process] is a rigorous one. Manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission.

518 U.S. at 477 (citations omitted). The Court contrasted this "rigorous" review with the 20 hours typical for a 510(k) review, *id.* at 479, and never addressed the preemptive scope of the PMA process.

In finding 510(k) approval not preemptive, the *Lohr* Court laid out a basic framework for analyzing express preemption under the MDA. First, a majority of the Court held that one needed to engage in a "careful comparison" of the details of the federal requirements applicable to the device and the state requirements that were arguably preempted. 518 U.S. at 500. Second, a majority of the Court specifically found that state common-law tort actions seeking damages *could* impose "requirements" and thus be preempted. See *id.* at 504-505 (Breyer, J., concurring); *id.* at 509 (O'Connor, J., concurring in part and dissenting in part). Finally, a majority of the Court found that only "specific" federal requirements could be preemptive, and only of "specific" state requirements. See *id.* at 500; *id.* at 506-507 (Breyer, J., concurring). Under this framework, the Court determined that approval through the 510(k) process — which focuses on "entirely generic concerns about device regulation generally" (*id.* at 501), that is, on the competitive disadvantage that would be caused if new items the substantial equivalent of a pre-

existing item were not easily marketable — did not preempt the state-law claims raised by the Lohrs.

Like *Lohr*, *Buckman* addressed preemption where a device had been approved through the 510(k) process. The plaintiffs in *Buckman* alleged that they were injured by a device manufacturer's "fraud on the FDA." But for fraudulent disclosures to the FDA, they claimed, the agency would not have approved marketing of a device, and thus plaintiffs would not have been injured. The Court — stressing that "although [*Lohr*] can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim" (121 S. Ct. at 1020) — found such claims to be impliedly preempted by the MDA. Fraud on a federal agency, the Court held, was not a matter historically of state concern, and "fraud-on-the FDA claims would * * * cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Agency, will later be judged insufficient in state court." *Id.* at 1019.

B. The Extensive Regulatory History Of The Model 4004M Device.

Both *Lohr* and *Buckman* stressed the "thorough review" (*Buckman*, 121 S. Ct. at 1015; see also *Lohr*, 518 U.S. at 477) that Class III medical devices must undergo before obtaining approval from the Food and Drug Administration pursuant to the PMA process. The path to approval of the Model 4004M pacemaker lead at issue in this case demonstrates the thoroughness of that review. When the FDA approved Medtronic's application for pre-market approval of the Model 4004M, on March 28, 1990, that approval was the culmination of a rigorous administrative process that began *eight years* earlier, with Medtronic's 1982 application for an investigational device exemption ("IDE") to permit clinical trials of the predecessor, Model 4003 lead. Before the FDA

determined, in approving the Model 4004M PMA, that Medtronic had proffered valid scientific evidence providing a reasonable assurance that the 4004M was safe and effective for its intended use, the device and its direct predecessor models (the Models 4004 and 4003) were rigorously reviewed and critically evaluated for safety and efficacy by the FDA, in light of the known and potential complications that could arise from their use, on numerous occasions between 1982 and 1990.

The following is a brief chronology of the FDA's review leading up to its approval of the Model 4004M.[1]

- Medtronic filed its initial IDE application for the Model 4003 lead on March 26, 1982.
- That application was denied by the FDA, in a letter dated May 6, 1982, pending submission of more detailed information regarding Medtronic's proposed clinical trial.
- Medtronic provided the requested information, and the FDA approved the IDE for the Model 4003 on June 28, 1982. The FDA prohibited any significant change in the investigation without advance FDA approval, however.
- Medtronic later requested authority to expand the clinical trial. In a June 29, 1983 letter, the FDA denied Medtronic's request, and required it to continue the investigation under the existing limits.
- Medtronic filed its PMA application for the Model 4003 lead on September 30, 1983. The application contained all of the detailed product and labeling information required by 21 C.F.R. §§ 814.20 *et seq*.

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[1] This description is based on the affidavit of Charles H. Swanson, J.A. 98-119; see also Pet. App. 3a-4a.

- FDA staff reviewed the Model 4003 PMA application, and by letter of November 29, 1983 required Medtronic to submit additional information concerning (1) the animal and *in vitro* testing of the lead so that FDA reviewers could better evaluate the testing, and (2) "the fate of the implanted lead, in terms of potential long term degradation of the insulating materials."

- Medtronic responded on February 14, 1984, providing detailed descriptions of completed testing as well as a compilation of published scientific literature and other relevant documents.

- On April 23, 1984, the FDA approved additional implants in the clinical trial, "for the purpose of determining whether or not to file a PMA," but required those implants to be performed by physicians who had particular experience recognizing potential complications from the leads.

- By letter of July 30, 1984, the FDA required Medtronic to supply additional information for its PMA review.

- Medtronic filed annual reports about the IDE trials of the 4003 lead yearly between 1983 and 1986.

- The FDA requested additional information about lead survival experience in the IDE investigation after receiving Medtronic's 1984 IDE annual report.

- In September 1985, Medtronic filed a supplement to the IDE, seeking FDA approval to permit fundamental design changes to be made in the lead and to revise the reporting requirements concerning field performance of the lead.

- Also in September 1985, Medtronic filed an amendment to its PMA application in response to the FDA's

July 30, 1984 letter. Medtronic furnished extensive data regarding the performance of prior lead models through its chronic lead performance database and through information gleaned from returned product analyses.

- The FDA approved the supplemental IDE in October 1985.
- The FDA demanded additional test and clinical data regarding the Model 4003 as a part of the PMA review in December 1985, and required amendments to the proposed warranty language.
- Medtronic responded in March 1986 by filing another supplemental PMA that explained in greater detail technical aspects of the lead's design, compared those with prior lead models, and analyzed data on the performance of those prior lead models. In addition, Medtronic provided an analysis of data generated from the clinical trials of the 4003 lead.
- In April 1986 — 30 months after Medtronic first filed a PMA request — the FDA advised Medtronic that the Model 4003 PMA was "suitable for filing," and would undergo the scientific and compliance review provided for in 21 U.S.C. §§ 360c, 360e(c)(2). The FDA also advised Medtronic that it would have to demonstrate that its facilities complied with all applicable "Good Manufacturing Practice" (GMP) rules and regulations under 21 C.F.R. Pt. 820.
- On May 23, 1986 the FDA referred the Model 4003 application to a panel of independent scientists for review. The panel concluded that Medtronic had submitted "valid scientific evidence" sufficient to be used to evaluate the safety and effectiveness of the Model 4003 lead. The panel members concluded that the information provided reasonable assurance that

the device was safe and effective for its intended use, and that the reports of complications and adverse reactions did not outweigh the benefits from use of the device.

- Based upon the record before it, the FDA approved the PMA application for the Model 4003 lead on July 29, 1986.

- The FDA formally acknowledged the closure of the IDE investigation for the Model 4003 lead in April 1987.

- On July 15, 1988, Medtronic filed a PMA application for the Model 4004 lead, as a supplement to the PMA for the Model 4003. The new application again complied in full with the requirements of 21 C.F.R. § 820.01 *et seq.* in both content and detail. In addition to providing extensive information on the new product's configuration, *in vitro* and *in vivo* testing of electrical performance, biostability test data, clinical test data about a prototype model tested in Canada, and copies of all proposed labels and warranty documents, Medtronic provided details of a newly-developed biostability test that replicated in a laboratory setting an insulation failure mode experienced in prior lead models. Appendices contained extensive data on lead survivability, both from Medtronic's "Chronic Lead Study" and from the analysis of prior lead models returned from the field.

- In response to this application, the FDA required Medtronic to modify the labeling of the Model 4004 to state explicitly that clinical trials had only been done on a unipolar version of the lead. Medtronic complied by submitting a revised label to the agency.

- The FDA approved the Model 4004 PMA Supplement on February 10, 1989, judging that Medtronic

had provided valid scientific evidence upon which it could conclude that the device was safe and effective for its intended use. The FDA required, as a condition of approval of the Model 4004 PMA, that a further PMA Supplement be filed before any change was made to the device that could affect its safety or effectiveness. In addition, the FDA required Medtronic to continue to report, post-approval, on the performance of the lead.

- Medtronic filed another PMA Supplement, seeking approval for the sale of the Model 4004M lead, on October 31, 1989, primarily to obtain approval to use a new type of connector pin at the end of the lead.

- The FDA approved the PMA for the Model 4004M lead on March 28, 1990, subject to the same conditions of approval that governed the approval of the Model 4004 lead.

Thus, the regulatory review under the PMA process that led to the approval of the Model 4004M lead lasted *eight years* — from March 1982 to March 1990 — and entailed detailed exchanges between the FDA and Medtronic to ensure that the agency was fully satisfied as to the testing, safety, design, and labeling of the Model 4004M and its predecessor models.

C. Petitioners' Case In The Lower Courts.

Elizabeth Kemp allegedly was injured when her Model 4004M lead malfunctioned. See Pet. App. 45a. Petitioners — Kemp and her husband, who filed only a derivative loss-of-consortium claim — thereafter brought this action against Medtronic in federal district court in Ohio on January 24, 1997. See *ibid.*

Petitioners' initial complaint raised 11 common-law and statutory product liability or derivative claims, alleging that the Model 4004M lead was defectively designed and manu-

factured and had inadequate warnings, that Medtronic had engaged in fraud and negligent misrepresentation under Ohio law, and that Medtronic had failed to comply with numerous FDA regulations. See Pet. App. 45a-46a. After pursuing discovery, however, petitioners narrowed their focus and placed emphasis on their negligence *per se* and fraud-on-the-FDA theories, challenging the sufficiency of Medtronic's submission of information in its PMA Supplement application, the accuracy of Medtronic's characterization of its scientific research findings and of the product's design, and Medtronic's post-approval regulatory compliance. Petitioners also contended that Medtronic made unauthorized changes to the design of the device, thereby rendering leads (such as Kemp's) made in conformance with the asserted modifications misbranded or adulterated, in violation of FDA regulations. See Brief of Plaintiffs-Appellants Elizabeth Kemp and Clifford Kemp, at 9-33, No. 99-3720 (6th Cir.) ("Brief of Appellants").

1. The District Court Proceedings.

On January 12, 1999, the district court granted Medtronic's motion for summary judgment, finding that the MDA preemption clause, 21 U.S.C. § 360k(a), preempted all claims raised in petitioners' complaint except to the extent those claims asserted that the device had not been manufactured in conformance with FDA requirements imposed by approving the device's PMA. Relying on *Lohr*, 518 U.S. at 495, the court held that state-law claims based on a violation of the FDA-approved specifications for the 4004M lead would not be preempted. However, the court held that petitioners had not specifically pled any such claim. See Pet. App. 66a-67a. The court therefore allowed petitioners to file "an amended complaint which alleges that the 4004M lead at issue deviated from the specifications approved by the FDA in the PMA and PMA Supplement." *Id.* at 67a.

Petitioners' amended complaint, however, restated the previously dismissed claims, as well as claims based on deviations from the approved specifications. See Pet. App. 72a. After dismissing the merely duplicative claims, on April 30, 1999, the court granted summary judgment on the new claims, holding as a factual matter that petitioners had presented no evidence that the Model 4004M failed to comply in any way with the FDA requirements applicable to the device, as established by its PMA process. *Id.* at 77a-80a.

2. The Court Of Appeals Decision.

On appeal to the Sixth Circuit, petitioners presented only three claims — negligence *per se*, fraud on the FDA, and the failure to warn petitioners of dangers based on information discovered after the PMA process. See Pet. App. 22a-37a; Brief of Appellants at 9-11, 49-63. The negligence *per se* claim, as "plaintiffs elected to distill" it below (Pet. App. 23a), alleged that "Medtronic failed to manufacture the Model 4004M as required by the FDA and thus sold a misbranded and/or adulterated product." *Id.* at 22a-23a. The fraud-on-the-FDA claim alleged that Medtronic "knowingly lied to the FDA and intentionally withheld information from the FDA in the application and approval process." Brief of Appellants at 61. The failure-to-warn claim, which was based on information "that Medtronic learned of * * * *after* the FDA's approval of the 4004/M PMA Supplement application and before implantation (and eventual failure) in Mrs. Kemp" (*ibid.*, emphasis supplied), alleged that Medtronic should have "issued additional or different post-sale warnings or timely recalled the product." *Id.* at 62. Petitioners also argued generally that if the Model 4004M as manufactured was different from the requirements approved by the FDA preemption should not be available. See *id.* at 49-52.[2]

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[2] Petitioners' brief below confirms that these three claims were in fact the only ones presented to the Sixth Circuit. For example, the

After carefully analyzing the opinions in *Lohr* (Pet. App. 11a-15a), the court of appeals determined that the FDA's express approval of the proposed design, labeling, and manufacturing of the Model 4004M — coupled with the statutory prohibition on modifying those requirements without FDA approval — established specific federal requirements applicable under the MDA to the device. See Pet. App. 21a. Recognizing that *Lohr* had held that "Congress intended the preemption of some state-law causes of action" (Pet. App. 20a), thereby triggering preemption under 21 U.S.C. § 360k(a)(1), the court then proceeded to address petitioners' claims one by one.[3]

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two-page introduction to petitioners' "Statement of Facts" explained the factual basis for their claims. According to petitioners:

- (1) "Medtronic made numerous misrepresentations to the FDA in its 4004/M PMA Supplement application in violation of FDA regulations and 21 U.S.C. §360e(b)." (Brief of Appellants at 9);
- (2) "Adding insult to injury, after FDA approval based on the above omissions and misrepresentations, Medtronic manufactured, marketed and sold a 4004/M *different* in design and manufacture from the 4004/M submitted to the FDA for review." (*Id.* at 10, emphasis in original); and
- (3) "In addition, Medtronic violated the FDA's general conditions of approval and FDA regulations in failing to provide the FDA with ongoing test results and relevant data which demonstrated that the 4004/M would fail. Medtronic obtained information post-approval that would have led any reasonable manufacturer to issue additional and/or different warnings and/or recall the product. Medtronic did nothing." (*Id.* at 10-11).

[3] In addition to express preemption arguments, Medtronic also made implied preemption arguments to the court of appeals (see, *e.g.*, Pet. App. 24a, 31a), but except with respect to the fraud-on-

The court of appeals rejected petitioners' negligence *per se* claims on several grounds. First, the court held that those claims had not been proven, because there was no evidence that Medtronic had violated the FDA's requirements in any fashion. See, *e.g.*, Pet. App. 25a (calling them "at best a tenuous assertion and, at worst, an outright mischaracterization of the record"). Second, the court held that "a jury verdict in plaintiff's favor on plaintiffs' negligence *per se* claims would amount to a state requirement 'different from, or in addition to,' the federal requirements" (*id.* at 30a), and thus found those claims preempted by § 360k(a). Finally, in the court's *per curiam* order denying petitioners' request for rehearing, the court determined that no such claims existed under Ohio law. See *id.* at 84a.[4]

The court of appeals disposed of petitioners' fraud-on-the-FDA claim by holding that it was expressly preempted by the MDA. See Pet. App. 34a-37a. Judge Moore agreed with this result but argued in her concurrence that the claim was instead impliedly preempted (see *id.* at 41a) — a ruling that the court's order denying rehearing seems to have adopted. See *id.* at 85a. Three weeks later, of course, this Court determined in *Buckman* that fraud-on-the-FDA claims such as petitioners were impliedly preempted by the MDA. See 121 S. Ct. at 1017.

Finally, the court of appeals held that petitioners' failure-to-warn claim was expressly preempted (Pet. App. 37a-38a) to the extent it challenged warnings approved by the FDA

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the-FDA claim the court focused exclusively on express preemption.

[4] In their petition for rehearing petitioners also attempted to expand the scope of their negligence *per se* claim. However, the court of appeals found that, "[t]o the extent that [petitioners] would have the Court view" their fraud-against-the-FDA claims also to be negligence *per se* claims, those claims did not state a cause of action for negligence *per se* under Ohio law. See Pet. App. 84a.

and that the claim was waived to the extent it was based on warnings that should have been developed as a result of analyzing data obtained *after* the FDA's approval. *Id.* at 38a. The court noted that "[i]t [was] difficult to determine * * * the underlying basis of plaintiffs' claim as presented to the district court below." *Id.* at 37a. In their petition for rehearing, petitioners clarified that on appeal they were raising specifically "a post-FDA approval failure to warn claim with a supporting factual basis" (Plaintiffs/Appellants' Petition for Rehearing With Suggestion For Rehearing *En Banc*, at 8), but the court held that this claim "should have been clarified below in a timely manner" (Pet. App. 86a) and therefore had been waived. See *id.* at 85a-86a.

REASONS FOR DENYING THE PETITION

Petitioners assert that review is necessary here because of the disarray in the lower courts over the interpretation of *Medtronic, Inc.* v. *Lohr*. But even if there were confusion about the preemptive scope of the MDA, this case would be a most inappropriate vehicle in which to resolve that confusion, because petitioners have presented no claims to this Court that were held preempted below (see Part I.A). Moreover, in light of this Court's recent decision in *Buckman*, the Court should allow the lower courts time to revisit preemption issues under the MDA (see Part I.B). Finally, as we explain in Part I.C, the lower courts are in significantly less disarray than petitioners suggest. In any event, given the extensive FDA scrutiny of the Model 4004M pacemaker lead, the Sixth Circuit's decision is plainly correct (see Part II).

I. THIS CASE DOES NOT PRESENT AN APPROPRIATE VEHICLE IN WHICH TO REVISIT *MEDTRONIC, INC.* V. *LOHR.*

A. Petitioners Have Preserved No Claims That Would Be Affected By This Court's Intervention.

"While this Court decides questions of public importance, it decides them in the context of meaningful litigation. Its function in resolving conflicts among the Courts of Appeals is judicial, not simply administrative or managerial." *The Monrosa* v. *Carbon Black Export, Inc.*, 359 U.S. 180, 184 (1959). Even if this Court were to adopt petitioners' interpretation of the MDA preemption provision, the judgment of the court of appeals would stand. Thus, were this Court to grant review, it would be in the position to deliver nothing but an improper advisory opinion.

Utterly missing from the petition is any real description of what claims the petitioners made below and how those claims were addressed. In fact, petitioners raised only three claims in the Sixth Circuit — fraud on the FDA, negligence *per se*, and failure to warn based on data learned after FDA approval, see page 11, *supra — none of which is before this Court.* Petitioners acknowledge that their fraud-on-the-FDA claim is preempted in light of *Buckman* and do not raise it in the petition. See Pet. 13 n.4. And they acknowledge that they cannot present their negligence *per se* claim to this Court, because that claim was partially "resolved on state-law grounds." *Ibid.*; see also *id.* at 8 n.2; Pet. App. 84a. Finally, petitioners' failure-to-warn claim was presented to the Sixth Circuit on the ground that Medtronic's failure to warn of evidence acquired after FDA approval violated state law (see Brief of Appellants at 33, 61-63) — but the court of appeals held that petitioners had waived such a claim. See Pet. App. 85a-86a. In sum, there is no claim preempted by the MDA that was both raised below and presented in the petition.

Even if petitioners had preserved product liability claims beyond their negligence *per se* claim, those claims would not present preemption issues to this Court. Petitioners' theory of product liability, which was developed through 20 months of discovery, see Brief of Appellants at 6, revolved around Medtronic's asserted failure to abide by FDA requirements. See *id.* at 10; *id.* at 32 ("Even if there is some type of specific federal requirement applicable to the 4004/M, Medtronic is still not entitled to preemption immunity. Medtronic marketed and sold a 4004/M different in manufacture and design than the 4004/M submitted for FDA review."); *id.* at 50-51. *The lower courts explicitly found, however, that Medtronic did not violate those requirements*. See Pet. App. 23a-27a; see, *e.g.*, *id.* at 25a ("[P]laintiffs' argument that the Model 4004M PMA Supplement included a specification that the platinum sputter coat would be a uniform 500 angstroms thick represents at best a tenuous assertion and, at worst, an outright mischaracterization of the record."). Thus, any remaining product liability claim that petitioners might attempt to assert, even if not preempted, was found to be factually unsupported.

The petition engages in an extensive academic discussion on the state of the law of MDA preemption, but it never explains how any of petitioners' claims that have evidentiary support in the record and that were not waived below would be affected by a favorable decision. (And it would, we believe, be most unfair for petitioners to attempt to provide that explanation for the first time in a reply brief, to which we would have no opportunity to respond.) Because the Court "'reviews judgments, not statements in opinions,'" *Johnson* v. *De Grandy*, 512 U.S. 997, 1003 n.5 (1994) (quoting *California* v. *Rooney*, 483 U.S. 307, 311 (1987) (*per curiam*) (quoting *Black* v. *Cutter Labs.*, 351 U.S. 292, 297 (1956))), there is no reason to grant certiorari.

B. This Court Should Allow The Lower Courts To Consider The Implications Of *Buckman* For MDA Preemption of State-Law Tort Actions Before Revisiting The Issue Itself.

While the *Buckman* Court, which focused on implied preemption, "express[ed] no view on whether [fraud-on-the-FDA] claims are subject to express pre-emption under 21 U.S.C. § 360k," 121 S. Ct. at 1017 n.2, this Court should nonetheless allow the lower courts time to consider the implications of *Buckman* before expending further effort on issues that the lower courts may resolve themselves in light of that case.

At least three aspects of the *Buckman* decision may assist courts in determining the preemptive scope of the PMA process. First, the Court in *Buckman*, as in *Lohr*, stressed how thorough the PMA process is as compared to the 510(k) process found non-preemptive in *Lohr*. See 121 S. Ct. at 1015. Second, the Court clarified that while *Lohr* "can be read to allow *certain* state-law causes of action that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim." *Id.* at 1020 (emphasis added). Finally, the Court discussed the "somewhat delicate balance of statutory objectives" that Congress sought to achieve under the MDA scheme and stressed how allowing state law claims of fraud-on-the-FDA would disrupt that balance. *Id.* at 1017.

All three aspects of *Buckman* may well influence lower courts' views about the preemptive effect of the PMA process. For example, the first reinforces the accuracy of the Sixth Circuit's holding that *Lohr*'s analysis of the preemptive scope of the 510(k) process is not applicable to the PMA process. Those few courts that have found otherwise may choose to reconsider those holdings in light of *Buckman*. See, *e.g.*, *Martin* v. *Medtronic, Inc.*, __ F.3d __, 2001 WL 682097, at *10 (5th Cir. 2001) (citing *Buckman* in contrast-

ing the 510(k) approval process with PMA review). Second, this Court acknowledged that at least some state-law claims must be preempted by the MDA; to the extent lower courts had found otherwise those courts may now conclude that they were incorrect. Finally, it is hard to see how the "delicate balance" cut by the MDA would not be disrupted by allowing states to impose conflicting requirements on devices approved by the FDA pursuant to the arduous PMA process. As the dissenting judge stressed in *Brooks* v. *Howmedica, Inc.*, 236 F.3d 956 (8th Cir.), *reh'g en banc granted*, 246 F.3d 1149 (8th Cir. 2001), allowing state-law failure-to-warn claims might impose "conflicting labeling requirements in various states" (*id.* at 968) that differed from the FDA's "unambiguous conclusion about how * * * competing considerations should be resolved" (*id.* at 967, quoting *Lohr*, 518 U.S. at 501).

The Eighth Circuit granted rehearing en banc in *Brooks*, where the majority had found failure-to-warn claims not to be preempted, *the day after this Court decided Buckman*. See 246 F.3d 1149. Just as that court now is reconsidering whether state-law claims against manufacturers of devices approved through the PMA process are preempted, so too other courts may decide to revisit the issue. Thus, rather than granting review in a procedurally problematic case on an issue that may never require this Court's attention, this Court should deny the petition.

C. While There Is Some Inconsistency In The Lower Courts, It Is More Limited Than Petitioners Assert.

Petitioners make a great deal about the "deep post-*Lohr* split in authority," asserting that there is a conflict "in two important and related respects." Pet. 14. Their first issue, however — "whether the FDA's grant of PMA for a medical device triggers preemption of state-law damages claims" (*ibid.*) — is in fact nothing but a confused summary of one

aspect of their second issue. That second issue in turn has two parts; petitioners assert that there are conflicts both on whether the PMA process imposes specific, federal requirements and whether any duties imposed through state-law damages actions can be preempted after *Lohr*. While some courts have misinterpreted *Lohr* on both what federal requirements may be preemptive and on whether state common-law claims may be preempted, the great weight of authority favors the Sixth Circuit's position on both issues.

1. On the "federal" side, *Lohr* held that "specific" federal requirements applicable to the device are preemptive under the MDA. See 518 U.S. at 500-501; Pet. App. 14a-15a.[5] Based on this Court's discussion of the "rigorous" nature of the PMA process, and this Court's comparison between 510(k)-process requirements (which the Court found to be "important but entirely generic concerns") and the PMA process (which fits in this Court's discussion of "the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements") (see *Lohr*,

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[5] In dissent, four Justices in *Lohr* observed that "[t]he statute makes no mention of a requirement of specificity, and there is no sound basis for determining that such a restriction on 'any requirement' exists." 518 U.S. at 512 (O'Connor, J., concurring in part and dissenting in part). We agree; in fact, the history of the FDA regulation relied on by the Court clearly shows that the "specificity" gloss was designed simply to ensure that a counterpart federal requirement *must be in existence* before a state requirement is preempted, not that the federal requirement must be device-specific. See Proposed Rules, *Exemptions From Federal Preemption of State and Local Device Requirements: Proposed Procedures for Consideration of Applications*, 42 Fed. Reg. 30,383 (June 14, 1977). However, the petition does not present this question, because even if specificity is required, the FDA's painstaking approval of the 4004M device through the PMA process easily satisfies that requirement. See pages 24-25, *infra*.

518 U.S. at 501), the vast majority of courts have found PMA approval and the resultant bar on changes to a FDA-approved device to create specific federal requirements that preempt conflicting state common-law damages actions. See, *e.g.*, Pet. App. 20a; *Martin*, 2001 WL 682097, at *10; *Brooks*, 236 F.3d at 963-964, *reh'g en banc granted on other grounds*, 246 F.3d 1149; *Mitchell* v. *Collagen Corp.*, 126 F.3d 902, 911 (7th Cir. 1997); *Worthy* v. *Collagen Corp.*, 967 S.W.2d 360, 376 (Tex. 1998); *Fry* v. *Allergan Med. Optics*, 695 A.2d 511, 516 (R.I. 1997); *Green* v. *Dolsky*, 685 A.2d 110, 117 (Pa. 1996).

Petitioners identify (at Pet. 16) only two federal courts of appeals or state courts of last resort (*cf.* S. Ct. R. 10) that did not find PMA approval to be preemptive — *Goodlin* v. *Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999), and *Weiland* v. *Telectronics Pacing Systems, Inc.*, 721 N.E.2d 1149 (Ill. 1999). The decisions in these cases, while inconsistent with the decision below, are internally confused and unlikely to survive even absent this Court's intervention.

For example, the *Goodlin* court found parts of the requirements imposed through the PMA process not to be "specific" (167 F.3d at 1376), while acknowledging that other aspects *were* specific (*ibid.*). The FDA's "conditions of approval," barring modification of a device without FDA consent, were specific federal requirements, the court acknowledged, but it found that these were not "'applicable under [the MDA] to the device.'" *Ibid.* (quoting 21 U.S.C. § 360k(a)(1)). This latter holding is not only inconsistent with the former holding but also contrary to *Lohr*, which focused on whether federal requirements were specific or general requirements, not whether they were applicable exclusively to the specific device. See 518 U.S. at 500 ("federal requirements must be 'applicable to the device in question" under FDA regulations). In fact, the FDA has frequently held that federal requirements have preemptive effect even though they apply to a wide array of devices. See, *e.g.*, Final

Rule, *Medical Devices*, 45 Fed. Reg. 67,321, 67,322 (Oct. 10, 1980).

Weiland, in contrast, found that all aspects of the PMA process were not specific. See 721 N.E.2d at 1152. It based that conclusion on two false premises, however: first, the court held that "premarket approval imposes no ascertainable substantive requirement on the manufacture or design of the device" (*ibid.*) — a statement that, while perhaps true for the device at issue in *Weiland*, certainly was not true in this case, where the FDA repeatedly required modifications of the product or its labeling (see pages 5-9, *supra*); second, the court held that the PMA process allows the FDA to assure only "the *minimal* safety of medical devices" (*id.* at 1153) (emphasis added), a holding inconsistent with *Lohr*, which understood the "reasonable assurance" of safety and effectiveness to be a significant hurdle. In light of *Buckman*'s repetition of the significance of PMA review, this decision is plainly incorrect.[6]

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[6] Petitioners' attempt to conflate the IDE process with the PMA process (see Pet. 16-17 n.5), to expand the scope of any conflict, should be rejected. Both of the decisions petitioners cite specifically discuss differences between the PMA process and the IDE process. See *Connelly* v. *Iolab Corp.*, 927 S.W.2d 848, 850 (Mo. 1996); *Niehoff* v. *Surgidev Corp.*, 950 S.W.2d 816, 818 (Ky. 1997). As the *Niehoff* court explained, the IDE process is designed "to encourage research and development" (950 S.W.2d at 818), while the PMA process includes "a determination that the product is safe and effective" (*ibid.*). Even were a state requirement not to be preempted based on the IDE process, then, the FDA's careful determination in the PMA process that a product is safe and effective in light of all known risks should still preempt conflicting state requirements, including requirements imposed through common-law tort actions. See *Lohr*, 518 U.S. at 501 ("The generality of [requirements imposed under the 510(k) process] make this quite unlike a case in which the Federal Government *has weighed the competing interests relevant to the particular requirement in ques-*

2. On the state side of the *Lohr* preemption equation, petitioners assert that there is a "profound" split of authority over whether state-law damages claims can ever be preempted by divergent federal requirements. In fact, the vast majority of lower courts have held that such claims can be preempted,[7] a decision that is plainly correct under *Lohr* (see pages 25-26, *infra*). Only one federal court of appeals or state court of last resort (*cf.* S. Ct. R. 10) has relied on a contrary finding to limit the preemptive scope of the MDA — the Tenth Circuit in *Oja* v. *Howmedica, Inc.*, 111 F.3d 782, 789 (1997). That case is one of the earliest appellate decisions to interpret *Lohr* and plainly misinterprets it in a variety of ways.[8]

For example, the Tenth Circuit never directly considered whether a finding of liability under a state-law duty would "have the effect of establishing a substantive requirement of a specific device" — even though the court earlier had acknowledged that such inquiry was necessary. 111 F.3d at

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tion, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.") (emphasis added).

[7] See, *e.g.*, Pet. App. 34a-35a, 37a; *Martin*, 2001 WL 682097, at *6; *Brooks*, 236 F.3d at 963, *reh'g en banc granted on other grounds*, 246 F.3d 1149; *Mitchell*, 126 F.3d at 913-914; *Papike* v. *Tambrands Inc.*, 107 F.3d 737, 741 (9th Cir. 1997); *Worthy*, 967 S.W.2d at 376-377; *Fry*, 695 A.2d at 517; *Green*, 685 A.2d at 117-118.

[8] The *Oja* court was confused not only about what state requirements may be preempted but also about what federal requirements are preemptive. Thus, though the court was confronted with a claim (for failure to warn) arising from a device approved, at the time it was implanted, through the 510(k) process, it held that the FDA's 510(k) review led to specific federal requirements — despite this Court's contrary holding in *Lohr*. See 111 F.3d at 789.

788 (quoting *Lohr*, 518 U.S. at 500 (in turn quoting 21 C.F.R. § 808.1(d)(1))). More important, the court failed to appreciate that a majority of this Court had expressly held in *Lohr* that state common-law damages actions impose "requirements" that can be preempted by federal requirements. See pages 25-26, *infra*.[9] This single aberrant decision by a federal court of appeals, rendered shortly after *Lohr*, does not warrant this Court's attention. There is no reason to believe that the Tenth Circuit would continue to follow *Oja* after further analysis of this Court's holding in *Lohr*, in light of the overwhelming weight of authority of other courts of appeals and the opinion of the FDA (see page 27 n.11, *infra*) that such state-law claims may be preempted.

II. THE DECISION BELOW, FINDING PREEMPTION OF STATE-LAW CLAIMS BASED ON THE REQUIREMENTS IMPOSED BY THE PMA PROCESS, IS PLAINLY CORRECT.

The decision below is consistent with *Lohr*, with Congress's intent in passing the MDA, and with common sense. Section 360k(a) prohibits any state "requirement" that is "different from, or in addition to, any requirement applicable under [the MDA] to the device" and "which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the MDA]." Thus, for preemption to occur there must be a federal requirement, a state requirement, and some "differen[ce]" be-

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[9] Petitioners' assertion that the Supreme Court of Kentucky, in *Niehoff*, 950 S.W.2d 816, held that state-law damages claims are not specific requirements is based on a quotation taken out of context and misread. Rather, the *Niehoff* court held that the IDE process (not the PMA process) imposes no specific *federal* requirement against which to compare Kentucky's common-law damages claims. See *id.* at 822. As discussed above (at n.6), the court also focused on the significant differences between the PMA process and the IDE process.

tween the two. See 518 U.S. at 500. Both criteria are satisfied here.

1. The Sixth Circuit correctly held that FDA approval of a medical device through the PMA process can create federal requirements applicable to the device that would preempt conflicting state requirements. Although the Court in *Lohr* did not directly reach that question, both the majority and the dissenting opinions are fully consistent with a finding that the PMA process can impose preemptive federal requirements. See 518 U.S. at 501 (discussing preemption where "the Federal Government has weighed the competing interests relevant to the particular requirement in question," in contrast to the 510(k) process); *id.* at 512 (O'Connor, J., concurring in part and dissenting in part) (disputing requirement that federal requirements need to be specific).

The decision below makes eminent sense. The PMA process imposes a host of specific federal "requirement[s]" on devices such as the Model 4004M lead.[10] We described above (at pages 5-9) the arduous eight-year process that led to the FDA's decision to approve Medtronic's plan to distribute the 4004M. That process entailed extended federal review and approval of "the product's design, testing, in-

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[10] Many provisions of the MDA refer to "requirements" imposed by the FDA through the PMA process (pursuant to 21 U.S.C. § 360(e). See 21 U.S.C. §§ 331(e), 360e(f)), 351(f)(1)(A)(i), 360(k)(2), 360c(b)(1)(A), 360c(c)(2)(A), 360c(e)(1)(B), 360e(b), 360e(c)(2), 360e(d)(2)(C), 360j(a), 360j(m)(2), 382(a)(2)(A). Under federal law, moreover, a device that is approved for marketing through the PMA process cannot be "manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. § 814.80; see also *id.* § 814.39. Put differently, the manufacturer is *required* to follow the design and other specifications embodied in the PMA application and approved by the FDA.

tended use, manufacturing methods, performance standards and labeling" and is "specific to the product." Pet. App. 18a, quoting *Mitchell*, 126 F.3d at 913. And most important, approval under the PMA entailed a finding, based on the FDA's painstaking review of an immense amount of scientific data, that "the device is both safe and effective." *Lohr*, 518 U.S. at 477, citing 21 U.S.C. § 360e(d)(2). The determination that a product is safe and effective, weighing "any probable benefit to health from the use of the device against any probable risk of injury or illness from such use (21 U.S.C. § 360c(a)(2)(C)), after a process characterized by the Supreme Court as "running the gauntlet" (*Lohr*, 518 U.S. at 494) and "exhaustive" (*Buckman*, 121 S. Ct. at 1018), is of necessity the determination that the details of that device are an appropriate compromise that should not be modified by state law.

Finally, Congress viewed the PMA process as imposing "requirements" that would trigger preemption. For example, prior to passage of the MDA, California's "Sherman Food, Drug, and Cosmetic Law" required pre-market approval of all new devices sold in the State. Congress specifically referred to this requirement as one that the FDA should allow to continue *by expressly exempting it* (under 21 U.S.C. § 360k(b)) from preemption by the PMA process. See H.R. REP. NO. 94-853, at 45-46. No such exemption would have been thought necessary were the PMA process not a requirement otherwise preemptive of the state law.

2. The Sixth Circuit also correctly found that petitioners' state-law claims, to the extent those claims were based on a showing that the device differed from the one required by the PMA, were preempted under § 360k. A majority of this Court held in *Lohr* that "the MDA will sometimes preempt a state-law tort suit" (518 U.S. at 503 (Breyer, J., concurring)), because "insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar

requirement that takes the form of a standard of care or behavior imposed by a state-law tort action" (*id.* at 504-505); accord *id.* at 509 ("state common-law damages actions do impose 'requirements' and are therefore pre-empted where such requirements would differ from those imposed by the FDCA.") (O'Connor, J., concurring in part and dissenting in part). The court below, like *Lohr*, found that state-law claims that impose a duty identical to federal requirements would not be preempted. See Pet. App. 33a. But where a state-law tort action is based on a requirement that is not identical to a federal requirement, that claim would seem definitionally to be "different from, or in addition to" (21 U.S.C. § 360k(a)(1)) the federal requirement. Here, the lower courts held that the PMA imposed a specific requirement on Medtronic to use platinum sputtering, but did not mandate that the sputtering be of a uniform 500 Å thickness. Were a jury to impose liability on Medtronic under Ohio law for not having kept its platinum sputtering at that uniform thickness, it would plainly be imposing a different, additional requirement on the 4004M pacemaker lead — and an additional requirement that could itself differ from requirements imposed in other states.

3. Putting aside the legalisms of *Lohr*, petitioners' position cannot possibly be consistent with Congress's decision to enact the MDA and to make that statute preemptive. The MDA strikes a careful balance between shielding the public "against unsafe, unproven, ineffective, and experimental medical devices" and ensuring that progress in the development of medical devices is not "stifle[d]" by "excessive or ill-conceived" regulation. H.R. REP. NO. 94-853, at 10; see also *FDA Oversight: Medical Devices: Hearing Before the Subcomm. on Oversight and Investigations of House Comm. on Energy & Commerce*, 97th Cong., 2d Sess. 5 (1982). A key element in striking this balance is Congress's delegation of exclusive authority to the FDA. Permitting state review and nullification of the FDA's PMA decisions would run

roughshod over this carefully calibrated enforcement scheme and would impose the "undu[e] burden[]" of differing state regulation that Congress aimed to avoid by including in the MDA a "general prohibition on non-Federal regulation." H.R. REP. NO. 94-853, at 45.[11]

* * * * *

In the final analysis, petitioners present this Court little evidence of a significant split in authority below, even less explanation for why the issue presented deserves the Court's attention at the present time, and no discussion whatsoever about the fact that no state-law claims preserved in their petition *were* preempted by FDA requirements imposed by the device's PMA. Thus, this Court is being asked merely to comment on a theoretical dispute about the scope of preemption under the MDA, rather than to resolve a specific issue in the context of active litigation.

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[11] In Part C of their brief, petitioners purport to present evidence of the United States' view on the questions presented herein. But the Solicitor General's view about whether *fraud-on-the-FDA* claims are expressly preempted, see Pet. 23-24, has no bearing on this case, where that claim — which raises significantly different concerns than product liability theories — has been dropped in light of *Buckman*. Similarly, the positions taken in the Solicitor General's brief in *Smith Industries Med. Systems, Inc.* v. *Kernats*, No. 96-1405, 118 S. Ct. 684 (1998) (Mem.), were based on the FDA's then-pending proposed rulemaking procedure. See United States Brief in *Kernats*, at 14, 19-20. The FDA has since withdrawn that proposed rule, see Pet. 23 n.8, and thus there is no evidence that those positions reflect the current views of the agency. In any event, petitioners' reliance on the views of the United States is selective. The Solicitor General has only recently taken the position that "Section 360k(a) does preempt a specific duty of care that is made applicable to a device through application in litigation of a State's common law of torts * * * ." United States Brief in *Buckman*, at 12 n.1.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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No. 00-1766

IN THE
Supreme Court of the United States

ELIZABETH KEMP AND CLIFFORD KEMP,
Petitioners,

v.

MEDTRONIC, INC.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit

REPLY BRIEF FOR PETITIONERS

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STATUTE

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REPLY BRIEF FOR PETITIONERS

The petition presents an important federal preemption question under the Medical Device Amendments ("MDA") that has divided the federal and state appellate courts. The deep split in authority is best exemplified by decisions of the Eleventh Circuit and the Sixth Circuit below that have arrived at diametrically opposed legal conclusions on the question presented in cases involving the same defendant and the same medical device. *See* Petition at 1. In opposition, respondent Medtronic, Inc. asserts that review should be denied because petitioners Elizabeth and Clifford Kemp did not properly preserve their claims and, even if they had, the split in authority does not warrant this Court's attention. As explained below, Medtronic's arguments are incorrect and the Court should grant the petition.

I. THE KEMPS HAVE PRESERVED THEIR PRINCIPAL PRODUCT LIABILITY AND NEGLIGENCE CLAIMS, ALL OF WHICH WOULD BE AFFECTED BY A RULING OF THIS COURT ON THE QUESTION PRESENTED.

As the Sixth Circuit below stated (8a), the courts are "sharply divided" on whether state-law product-liability and negligence claims, such as those alleging defective design and manufacture and failure to warn, are preempted by the MDA, where the device in question was granted pre-market approval ("PMA") by the Food and Drug Administration ("FDA"). Medtronic's principal argument against review is that the Kemps did not preserve any such claims in the Sixth Circuit and thus those claims are not before this Court. Medtronic is flatly incorrect.

The Kemps' complaint contained multiple causes of action, including "strict liability based on defective manufacture, design, and warning" (45a), negligent testing, manufacture, and design of the 4004M lead (45a), a separate

count alleging that "Medtronic failed to warn the Plaintiffs of dangerous risks involved in the use of the 4004M lead" (45a), and another alleging that Medtronic breach implied warranties in its design and marketing of the lead. 46a; *see generally* Complaint in *Kemp v. Medtronic, Inc.*, No. C-1-97-0103 (S.D. Ohio filed Jan. 24, 1997). On January 12, 1999, the district court granted summary judgment to Medtronic on the Kemps' claims of defective manufacture (57a), defective design (60a), failure to warn (60a-61a), and implied warranty (68a) on federal preemption grounds. At the same time, the district court also granted the Kemps leave to amend their complaint to make additional allegations in support of a negligence per se claim (67a).

The Kemps then filed an amended complaint regarding the negligence per se claim and also reiterated each of their general causes of action. The Kemps asked "the [district] Court to revisit its [earlier preemption] ruling" regarding the general state-law design, manufacturing, failure to warn, and implied warranty claims (80a), relying on the Eleventh Circuit's recent ruling in *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999), which also involved Medtronic's 4004M lead and held that the MDA does not preempt such claims. On April 30, 1999 (70a), the district court granted summary judgment to Medtronic on the negligence per se claim and rejected the Kemps' request for reconsideration. The district court entered judgment for Medtronic on all claims and dismissed the case with prejudice (82a).

Thereafter, the Kemps filed a notice of appeal, which explicitly appealed from the district court's January 12 order on the general product liability and negligence claims as well as the April 30 ruling that had reaffirmed that holding and rejected the negligence per se claim.. *See* Notice of Appeal ¶¶ 1, 3 in *Kemp v. Medtronic, Inc.*, No. C-1-97-0103 (S.D. Ohio filed May 28, 1999). The Sixth Circuit affirmed the district court's

summary judgment ruling in its entirety. It explicitly noted the Kemps' general product liability and negligence claims (54a), and did not remotely suggest that the Kemps had waived those claims. The court then made the "threshold" determination that the PMA process establishes "specific federal requirements" that have preemptive effect under this Court's decision in *Lohr* (15a-22a). The Sixth Circuit thus "agree[d]" with Medtronic that "the design, manufacturing processes, and labeling" involved in the PMA process are federal requirements that have preemptive effect (21a-22a), and it explicitly rejected the Eleventh Circuit's contrary ruling in *Goodlin*. 18a. Thereafter, in a section labeled "Plaintiffs' Claims," the Sixth Circuit dealt only with the Kemps' negligence per se, fraud on the FDA, and failure to warn claims (22a-38a). If taken in isolation, this portion of the court of appeals' opinion could lead a reader to believe that the Kemps had pled *only* those claims, but, as indicated above, that would be plainly wrong and the preceding portions of the Sixth Circuit's opinion effectively reject the Kemps' design and manufacturing defect claims on the ground that the PMA process establishes federal preemptive "requirements."

In any event, regardless of how the Sixth Circuit parsed the Kemps' claims, there is no doubt that the Sixth Circuit's judgment affirmed the district court's rulings in their entirety, including the rulings rejecting the Kemps' general product liability and negligence claims, on preemption grounds. Recognizing that critical fact, Medtronic asserts that the Kemps raised only the negligence per se, fraud-on-the-FDA, and failure-to-warn claims in their Sixth Circuit brief. Based on that premise, Medtronic maintains that, because the Sixth Circuit resolved each of those claims on non-preemption grounds, the Kemps are seeking an advisory opinion on MDA preemption that would have no effect on their claims. Opposition at 15.

The premise of Medtronic's argument is simply wrong. The Kemps vigorously pursued *all* of their claims in the Sixth Circuit. Indeed, the *first* argument in the Kemps' appellate brief states that "There is No Preemption Immunity for a Manufacturer of a Medical Device by Virtue of Approval of a PMA Supplement Application." Brief of Plaintiffs-Appellants at 34 in *Kemp v. Medtronic, Inc.*, No. 99-3720 (filed Jan. 11, 2000). The Kemps maintained that *none* of their claims is preempted "Because there are no Federal Requirements Applicable to the 4004/M as a Result of the PMA Supplement Application Process." *Id.* at 40. In making this argument, the Kemps relied on the Eleventh Circuit's decision in *Goodlin*, *id.* at 41, which held that the PMA process does not establish specific federal requirements that preempt state-law design, manufacturing, and failure-to-warn claims. The Kemps argued that "[t]he FDA's issuance of a generic form approval letter does not mean that the FDA has established specific design and manufacturing requirements." *Id.* at 44. Thus, because the FDA did not promulgate "federal regulations regarding the manufacture and design of pacemaker leads," "there is no preemption immunity under Section 360k." *Id.* at 45.

The Kemps also argued in the Sixth Circuit that *none* of their claims is preempted because their state product-liability and negligence claims are not sufficiently specific to trigger preemption under *Lohr*. *Id.* at 45. The Kemps ended this argument by stating that their claims are "indisputably based on duties of general applicability of Ohio common law and Ohio's product liability act," *id.* at 48, and therefore are not preempted, an explicit reference to their "claim under Ohio law for strict liability based on defective manufacture, design, and warning." *See* 45a & n.2.

It was only *after* the Kemps maintained that none of their claims is preempted, beginning on page 52 of their appellate brief, that they turned to their alternative argument:

"Regardless of Whether the FDA's Approval of the 4004/M PMA Supplement Establishes Specific Federal Requirements, Medtronic Was Not Entitled To Summary Judgment on All of Plaintiffs' Claims." The Kemps then explained why, even if there was some preemption, their claims based on negligence per se, fraud on the FDA, and failure to warn of post-approval information are not preempted. *See id.* at 52-63. Thus, in concluding their brief, the Kemps asked the Sixth Circuit to reverse the district court's order "on *all* of Plaintiffs' claims." *Id.* at 63 (emphasis added).

In sum, the Kemps' general product liability and negligence claims — the very kinds of claims about which the federal and state courts are divided in MDA preemption cases — were argued to the Sixth Circuit and dismissed as a result of the Sixth Circuit's judgment. Therefore, they are properly before this Court.[1]

II. THE QUESTION PRESENTED INVOLVES A DEEP AND UNRESOLVED SPLIT IN AUTHORITY THAT CALLS FOR RESOLUTION BY THIS COURT AT THIS TIME.

Medtronic contends that the Court should deny review because this Court's recent decision in *Buckman Company v. Plaintiffs' Legal Committee*, 121 S. Ct. 1012 (2001), may alter

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[1]Medtronic's assertion that the Kemps preserved their failure-to-warn claim only to the extent that it alleged a failure to warn of information known to Medtronic after approval of the 4004M lead is particularly odd. The Sixth Circuit held that the Kemps did not adequately plead that aspect of the claim and therefore did not reach the preemption issue regarding it (38a). However, the Sixth Circuit also held that the claim that Medtronic failed to warn of information known at the time of the 4004M's approval is preempted by the MDA (37a). That claim is therefore properly before this Court.

the legal terrain and because the split in authority among the lower courts in not as serious as the Kemps maintain. Neither contention is persuasive.

A. Medtronic asserts that the Court should defer review because *Buckman* "may assist [lower] courts" in resolving the question presented. Opposition at 17. Medtronic ignores the key reason why *Buckman* is irrelevant here: In holding that a fraud-on-the-FDA claim is impliedly preempted by federal law, *Buckman* explicitly distinguished claims, such as those at issue here, that "rely[ ] on traditional state tort law which had predated the federal [MDA] enactments in question." 121 S. Ct. at 1020.

Beyond that basic omission, Medtronic makes three points related to *Buckman*, none of which has merit. First, it notes that in *Buckman,* "as in *Lohr*," the Court "stressed" the difference between the PMA process and the 510(k) process. Opposition at 17. Actually, *Buckman* mentioned that point only in passing, 121 S. Ct. at 1017; *Buckman* had nothing to do with the PMA process because the device there was a 510(k), not a PMA, device. *Id.*

Second, Medtronic claims that *Buckman* clarified that, under *Lohr*, only "certain" state-law causes of action that parallel federal requirements may go forward. Opposition at 17. That supposed clarification also has nothing to do with this case, because the Kemps are not pursuing claims that purport to parallel federal requirements, *see* Petition at 8 n.2; instead, they rely exclusively on general state-law claims regarding manufacturing and design defect and failure to warn. Equally important, the principal cases reflecting the deep divide among the lower courts also involve those kinds of claims. S*ee, e.g., Goodlin*, 167 F.3d at 1369; *Oja v. Howmedica*, 111 F.3d 782, 784-85 (10th Cir. 1997); *Weiland v. Telectronics Pacing Sys., Inc.*, 721 N.E.2d 1149, 1151 (Ill. 1999); *Martin v. Medtronic, Inc.*, __ F.3d __, __, 2001 WL 682097, *1 (5th Cir. 2001).

Thus, none of those precedents could possibly be affected by *Buckman*'s comment regarding state-law causes of action that parallel federal requirements.

Third, Medtronic relies on *Buckman*'s statement that a state-law fraud-on-the-FDA claim would disrupt the balance that Congress was trying to achieve under the MDA. Opposition at 17. We fail to see how that point relates to the question presented here — whether 21 U.S.C. 360k(a) expressly preempts the Kemps' claims based on "traditional state tort law." *Buckman*, 121 S. Ct. at 1020. In this regard, it is important to consider what was at issue in *Buckman*. The plaintiff in *Buckman* relied solely on a fraud-on-the-agency theory, rather than a traditional tort theory, because the defendant was not the device manufacturer, but rather a regulatory consultant who had no relationship with the medical device patients or their physicians. The theory of the case was unrelated to whether the product was properly designed or manufactured or accompanied by appropriate warnings, but was premised entirely on the notion that the product would not have been marketed if not for the consultant's fraudulent submissions to the FDA. Thus, the Court's concern about the balance struck by Congress related to the potential for interference with the internal workings of the FDA, *id.*, not with the independent tortious conduct of device manufacturers in their interactions with device users and physicians, as is the case here. Moreover, the Court's ruling was based solely on *implied preemption* principles and did not even discuss whether a fraud-on-the-FDA claim, let alone the "traditional state law tort" claims at issue here, is preempted by the MDA's express preemption provision, 21 U.S.C. 360k(a). Indeed, *Buckman*'s only reference to section 360k(a) is in a footnoted sentence stating that the Court would *not* consider the question whether a fraud-on-the-FDA claim is expressly preempted. 121 S. Ct.

at 1017 n.2. In sum, the fraud-on-the-FDA ruling in *Buckman* has no bearing on the question presented here.[2]

B. Even farther afield is Medtronic's speculation that courts that have rejected preemption may revisit their no-preemption holdings, and that therefore this Court should deny review because the split in authority will go away. Absent a decision of this Court finding preemption on the question presented, there would be no lawful basis for such an about-face. Indeed, we know of no case in the Tenth Circuit (where *Oja* prevails) or in the Eleventh Circuit (where *Goodlin* prevails) in which the defendant device manufacturer is arguing that *Buckman* or some other development requires that circuit precedent be set aside, and presumably Medtronic — the world's largest device manufacturer and a frequent litigant — would have brought such cases to this Court's attention if there were any. In the federal system, the no-preemption circuit precedents may only be reversed en banc. That would require the defendant to lose a trial on the merits, appeal on preemption grounds, and convince an en banc court to overrule existing

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[2] Medtronic contends that recent decisions demonstrate that *Buckman* is having an effect on express preemption analysis under the MDA. Just the opposite is true. Despite Medtronic's suggestion to the contrary, Opposition at 17-18, the Fifth Circuit's recent decision in *Martin,* 2001 WL 682097 — which involved the exact same issue as presented here regarding the 4004M lead — did not rely on *Buckman* in any respect. Similarly, *Brooks v. Howmedica, Inc.*, 226 F.3d 966 (8th Cir. 2001), involved solely the question whether a traditional state-law failure-to-warn claim is expressly preempted by section 360k(a). The fact that rehearing en banc was granted in *Brooks* the day after *Buckman* was decided, *see* Opposition at 18, is obviously happenstance, unless we are to believe that, sensing a need to act immediately, the full complement of Eighth Circuit judges read this Court's decision, conferred, and granted the en banc petition within 24 hours.

circuit precedent. Thus, the notion that this Court should deny review on the ground that the Tenth and Eleventh Circuits will reverse themselves, eliminating any federal circuit conflict, does not hold water. The chance that the state courts will overrule their no-preemption holdings, *see* Petition at 16, 18-19, is even more remote, because those courts have already heard the matter en banc and are extremely unlikely to reverse course absent an authoritative ruling on the express preemption issue presented in this petition.[3]

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[3]Medtronic's argument that the current split in authority is not significant, Opposition at 18-23, is fully answered by the petition (at 14-19). Although Medtronic purports to deny a significant split, Opposition at 18, Medtronic's main thrust is actually a critique on the merits of the key decisions with which it disagrees. *Id.* at 18-23. That the courts have taken differing views on the merits, however, only underscores the need for review. *See infra* Part III. As to the split in authority, we reiterate that, in December 1997, *before* the Eleventh Circuit's decision in *Goodlin* and the Illinois Supreme Court's decision in *Weiland*, the Solicitor General maintained that the "current division" in the courts would have called for review by this Court, except for unusual circumstances not present here. *See* Petition at 23 (discussing Solicitor General's amicus brief in *Smith Industries Medical Systems v. Kernats*, No. 96-1405). Medtronic's assertion that the government's position on the merits in *Kernats* was based on the pendency of a now-withdrawn proposed FDA regulation is flatly incorrect. The Solicitor General argued at length that the no-preemption decision in *Kernats* was correct. That merits argument was unrelated to the proposed regulation, *see* United States Brief in *Kernats*, at 14-18, which was discussed at the very end of the brief only as a reason to deny review. *Id.* at 19-20.

III. THE RULING BELOW ON THE MERITS UNDERSCORES THE NEED FOR REVIEW.

The petition briefly explains why the ruling below on the merits is inconsistent with the text and purpose of the MDA and this Court's decision in *Lohr*. Petition at 20-22. Medtronic, of course, argues that the ruling below is correct. Opposition at 20-23. The parties' disagreements are quite stark. For instance, while Medtronic argues that FDA pre-market approval transforms all specifications of the manufacturer's application into preemptive federal requirements, Opposition at 24, the Kemps maintain that such specifications originate with the manufacturer, not FDA, and thus are not specific federal requirements that have preemptive force (as contrasted with certain FDA regulations applicable to particular devices). Petition at 21. The petition and opposition reveal the parties' drastically different understanding of the law and the significance of the facts concerning approval of the 4004M lead. If this Court grants review, there will be time enough to reply to Medtronic's merits arguments in detail. However, for present purposes, the depth of the disagreement on the merits only underscores the need for review. As is evident from the parties' submissions, some courts have sided largely with the Kemps on the merits and others largely with Medtronic. Their positions are irreconcilable and can only be resolved through this Court's intervention.

CONCLUSION

For the reasons stated above and in the petition, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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